

Exhibit 116



Screening Assessment

Talc
(Mg₃H₂(SiO₃)₄)

Chemical Abstracts Service Registry Number
14807-96-6

Environment and Climate Change Canada
Health Canada

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Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of talc. The Chemical Abstracts Service Registry Number (CAS RN¹) for talc is 14807-96-6. This substance is among those substances identified as priorities for assessment as it met categorization criteria under subsection 73(1) of CEPA.

Talc is a naturally occurring mineral. In 2011, talc was manufactured in Canada in quantities ranging between 50 to 75 million kg, and in 2016, approximately 100 million kg of talc was imported into Canada. In Canada, talc is used in adhesives and sealants; automotive, aircraft, and transportation applications; building and construction materials; ceramics; electrical and electronics; textiles; floor coverings; inks, toners, and colourants; lubricants and greases; oil and natural gas extraction applications; paints and coatings; paper and paper products, mixtures, and manufactured items; plastic and rubber materials; toys, playground equipment and sporting equipment; and in water treatment. The major uses in Canada align with major global uses of talc. Talc is a permitted food additive and is an ingredient in self-care products. In North America, approximately 2% to 4% of the talc produced and sold is used in cosmetics. High-purity talc is used in self-care products including cosmetics, while lower-grade talc is used in commercial applications.

The ecological risk of talc was characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard characterization in ERC-I included a survey of published predicted no-effect concentrations (PNECs) and water quality guidelines, or the derivation of new PNEC values when required. Exposure profiling in ERC-I considered two approaches: predictive modelling using a generic near-field exposure model for each substance and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. Modelled and measured predicted environmental concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment. Based on the outcome of the ERC-I analysis, talc is considered unlikely to be causing ecological harm.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to the environment from talc. It is concluded that talc does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering the

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environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Talc has been reviewed internationally by other organizations, including the International Agency for Research on Cancer (IARC) and the Danish Environmental Protection Agency. These assessments informed the human health risk assessment.

No critical health effects were identified via the oral or dermal routes of exposure. As such, oral exposure to talc resulting from food intake and oral and dermal exposure from the use of self-care products are not of concern. Inhalation exposure via ambient air for the general population from industrial and commercial uses of talc was not identified to be of concern for human health given the limited number of sites producing and processing talc in Canada. Rather, the focus of the assessment is on inhalation and perineal exposure to certain self-care products containing cosmetic- or pharmaceutical-grade talc.

With respect to inhalation exposure, non-cancer lung effects (e.g., inflammation, impaired lung function, fibrosis) were identified as a critical health effect for risk characterization on the basis of United States National Toxicology Program studies conducted with rats and mice exposed to cosmetic-grade talc. There is potential for inhalation exposure to talc powder during the use of certain self-care products (e.g., cosmetics, natural health products, non-prescription drugs formulated as loose powders). Self-care products formulated as pressed powders (e.g., face makeup) are not of concern for inhalation exposure. Margins of exposure between air concentrations following the use of dry hair shampoo and foot powder and critical lung effects observed in animal studies are considered adequate to address uncertainties in the health effects and exposure databases. Margins of exposure between air concentrations following the use of body powder, baby powder, and loose face powder and critical lung effect levels observed in animal studies are considered potentially inadequate to address uncertainties in the health effects and exposure databases.

With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are indicative of a causal effect. Given that there is potential for perineal exposure to talc from the use of certain self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), a potential concern for human health has been identified.

Considering all the information presented in this screening assessment, it is concluded that talc meets the criteria under paragraph 64(c) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that talc meets one of the criteria set out in section 64 of CEPA. It has also been determined that talc meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

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1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of talc to determine whether this substance presents or may present a risk to the environment or to human health. This substance was identified as a priority for assessment as it met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017]).

The ecological risk of talc was characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I) (ECCC 2018), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard characterization in ERC-I included a survey of published predicted no-effect concentrations (PNECs) and water quality guidelines, or the derivation of a new PNEC value when required. Exposure profiling in ERC-I considered two approaches: predictive modelling using a generic near-field exposure model for each substance and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. Modelled and measured predicted environmental concentrations (PECs) were compared to PNECs, and multiple statistical metrics were computed and compared to decision criteria to classify the potential for causing harm to the environment.

With respect to human health, this screening assessment includes the consideration of information on chemical properties, environmental fate, hazards, uses, and exposures, including additional information submitted by stakeholders. Relevant data were identified up to October 2020. Empirical data from key studies, as well as results from models, were used to reach conclusions. Talc has been reviewed internationally through the International Agency for Research on Cancer (IARC) Monographs Programme, the United States Environmental Protection Agency (U.S. EPA), the Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) Expert Committee on Food Additives (JECFA), and the Danish Environmental Protection Agency (Danish EPA). Talc was also assessed by the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK-Commission) in Germany and the Cosmetic Ingredient Review (CIR) Expert Panel.² These evaluations and reviews were used to inform the health effects characterization in this screening assessment. This assessment focuses on health effects associated with cosmetic- and pharmaceutical-

² The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America.

grade talc and not on potential impurities, such as asbestos. Engineered nanomaterials composed of or containing talc are not explicitly considered in this assessment.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and in the Consumer and Hazardous Products Safety Directorate at Health Canada and incorporates input from other programs within these departments. Health Canada scientists conducted research to characterize airborne particles emitted during application of cosmetic talc products (Rasmussen et al. 2019). This peer-reviewed published research has informed the assessment. The ecological portion of the assessment is based on the ERC-I (published May 11, 2018), which was subject to an external peer review and a 60-day public comment period. The human health portion of this assessment has undergone external peer review. Comments on the technical portions relevant to human health were received from T. Lopez, MSPH, K. Super, DABT, and Z. Jeney, MPH, of Tetra Tech. Additionally, the draft of this screening assessment was subject to a 60-day public comment period. Additional information submitted during the public comment period was reviewed and considered for the final screening assessment. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight of evidence approach and precaution.³ This screening assessment presents the critical information and considerations on which the conclusion is based.

2. Identity of substance

Talc (CAS RN⁴ 14807-96-6) is one of the softest naturally occurring minerals, made up of magnesium, silicon, hydrogen and oxygen (ChemIDplus 1993-). The term talc refers

³ A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other acts.

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to both the pure mineral and a wide variety of soft, talc-containing rocks that are mined and used for a variety of applications (Kogel et al. 2006). Relatively pure talc ore is also referred to as steatite, and soapstone refers to impure, massive talc rock (Fiume et al. 2015).

The mineral talc is composed of triple-sheet crystalline units, consisting of two silicate sheets composed of SiO_4 tetrahedra joined by edge-linked $\text{MgO}_4(\text{OH})_2$ (Zazenski et al. 1995). These layers, held together loosely via van der Waals forces, slide over one another easily, giving talc its slippery feel and accounting for its softness (Fiume et al. 2015). The size of an individual talc platelet (i.e., a few thousand elementary sheets) can vary from approximately 1 μm to over 100 μm , depending on the conditions of formation of the deposit (EuroTalc 2017). The individual platelet size determines the lamellarity of a sample of talc. Highly lamellar talc will have large individual platelets, whereas microcrystalline talc will have small platelets. Other inorganics in place of magnesium and silicon are common in talc; for example, aluminum and iron may substitute for silicon in the tetrahedral sites, or manganese may substitute for magnesium in the octahedral positions (Zazenski et al. 1995).

Commercially exploited talc contains 20% to 99% of the pure mineral (Kogel et al. 2006). Some of the most common minerals that occur with talc are carbonates (e.g., dolomite, calcite, magnesite) and chlorite (i.e., magnesium aluminum silicate) (CIR 2013). Less common minerals include quartz, mica, iron oxides, pyrite, serpentine, and amphibole. Selective mining, ore processing, and beneficiation can remove many of the impurities (Kogel et al. 2006). There is a trend towards upgrading to higher-purity talc; however, many applications require the properties of the minerals associated with talc (Kogel et al. 2006) and the purity of the source talc influences its uses.

There are different grades of talc that refer to the purity (presence of other minerals). Pharmaceutical-grade talc complies with the United States Pharmacopeia (USP) standards (or similar standards), which require the absence of asbestos and set limits on iron, lead, calcium, and aluminum (USP 2011). As per B.01.045 of the *Food and Drug Regulations*, when used as a food additive, talc must meet the food-grade specifications set out in with the most recent edition of the *Food Chemicals Codex*, published by the United States Pharmacopeial Convention or the *Combined Compendium of Food Additive Specifications*, prepared by the Joint FAO/WHO Expert Committee on Food Additives, and must be free from asbestos (Canada [1978]; FAO 2006; FCC 2016).

Historically, some talc source materials were contaminated with asbestos. However, in 1976, the Cosmetic Toiletry and Fragrance Association (CTFA) set purity standards for cosmetic-grade talc resulting in a reduction in asbestos levels in cosmetic products (Fiume et al. 2015). Cosmetic-grade talc should comply with USP standards that require a limit of 20 ppm lead and an absence of asbestos (Fiume et al. 2015). Currently the USP standard for talc is under review (USP 2019; USP 2020a, USP b) and the United States Food and Drug Administration (U.S. FDA) is working on recommendations on

testing methods for asbestos in talc and products available to consumers containing talc (U.S. FDA 2020a). Internationally, a number of regulatory agencies continue to conduct testing on talc-based cosmetic products for the presence of asbestos (NVWA 2018; U.S. FDA 2020b).

In Canada, the *Prohibition of Asbestos and Products Containing Asbestos Regulations* (updated 2018) under CEPA prohibit asbestos above trace levels in products available to consumers, including cosmetics. The cosmetic-grade talc used in the health effect studies cited in this assessment were considered to be free of asbestos.⁵

Talc is milled to different particle sizes for specific commercial applications. Most talc for cosmetics and pharmaceuticals is pure 200-mesh roller-milled talc (Kogel et al. 2006). In 200-mesh talc (preferred for body powder and deodorants), the particle size distribution allows 95% to 99% of the product to pass through a 200-mesh (74 µm) screen (Zazenski et al. 1995; Kogel et al. 2006). The finer 325-mesh talc is also used in cosmetic-, pharmaceutical-, and food-grade formulations, where 95% to 99% of the product passes through a 325-mesh (44 µm) screen.

3. Physical and chemical properties

A summary of physical and chemical properties of talc is presented in Table 3-1. Talc is a chemically inert, solid powder that is insoluble in water (Kogel et al. 2006, EuroTalc 2017).

Table 3-1. Experimental physical and chemical property values (at standard temperature) for talc

Property	Range	Key reference
Physical state	solid, powder	HSDB 2005
Melting point (°C)	1500	EuroTalc 2017
Vapour pressure (mm Hg)	approx. 0, negligible at 20°C	OSHA 1999; NIOSH 2014
Water solubility (mg/L)	Insoluble	HSDB 2005
Specific gravity (unitless)	2.58–3.83	HSDB 2005

4. Sources and uses

Talc is a naturally occurring mineral, and there are talc deposits in most Canadian provinces (Kogel et al. 2006). Currently, there is one producing mine (open-pit) and

⁵ met the USP standards for absence of asbestos

concentrator facility in Canada, in Penhorwood Township near Timmins, Ontario, and one micronizing facility in Timmins (Kogel et al. 2006; MAC 2019; NPRI 2018). The talc ore from the mine is approximately 45% pure, with magnesite, magnetite, chlorite, and serpentine as the major impurities (Kogel et al. 2006). After beneficiation, this mine and micronizing facility produces talc primarily for the paper, plastics, paint, and ceramic sectors (Kogel et al. 2006). In 2019, China was the largest producer of talc, followed by India and Brazil (USGS 2020). The major uses of talc globally include paper, plastics, paint, ceramics, putties, and cosmetics (USGS 2000; Kogel et al. 2006; EuroTalc 2017; USGS 2020).

Talc was included in a survey issued pursuant to a CEPA section 71 notice. Talc was reported to be manufactured in Canada at quantities ranging from 50 to 75 million kg in 2011 (EC 2013).⁶ According to the Canadian International Merchandise Trade (CIMT) database, in 2016, 99 549 000 kg of natural steatite and talc, crushed or powdered (Harmonized System, HS code 252620) and 4 656 000 kg of natural steatite and talc, not crushed, not powdered (HS code 252610) were imported into Canada (CIMT 2017).

According to information submitted in response to a CEPA section 71 survey (EC 2013), results from voluntary stakeholder engagement (ECCC, HC 2017), and a search of websites from talc producers, manufactured or imported talc is used in Canada in adhesives and sealants; automotive, aircraft, and transportation applications; building and construction materials (e.g., wood and engineered wood); ceramics; electrical and electronics; textiles; floor coverings; inks, toners, and colourants; lubricants and greases; oil and natural gas extraction applications; paints and coatings; paper and paper products, mixtures, or manufactured items; plastic and rubber materials; toys, playground equipment and sporting equipment; and in water treatment.

Talc is a formulant in pest control products registered in Canada (Health Canada 2010; personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the Risk Management Bureau, Health Canada, dated March 29, 2017; unreferenced).

Additionally, in Canada talc is on the *List of Permitted Food Additives with Other Accepted Uses* (List 8) for limited uses in a small number of foods (Health Canada [modified 2020]). Talc can be used as a coating agent on dried legumes and rice and as a filler and dusting powder for chewing gum as per the *List of Permitted Food Additives with Other Accepted Uses*, incorporated by reference into its respective Marketing Authorization issued under the *Food and Drugs Act*. It may be used as a component in

⁶ Values reflect quantities reported in response to the survey conducted under section 71 of CEPA (EC 2013). See survey for specific inclusions and exclusions (schedules 2 and 3).

the manufacture of food packaging materials and as a component in incidental additives⁷ used in food processing establishments with no food contact (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 31, 2017; unreferenced).

Talc is present in approximately 10 000 self-care products.⁸ It is used as a non-medicinal ingredient in approximately 1700 marketed or approved human and veterinary drug products in Canada, including approximately 150 non-prescription drugs (email from the Natural and Non-Prescription Health Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada, dated November 18, 2020; unreferenced). Talc is listed in the Natural Health Products Ingredients Database (NHPID) with a medicinal role and classified as a natural health product substance falling under item 7 (a mineral) of Schedule 1 to the *Natural Health Products Regulations*, as well as with a non-medicinal role for use as abrasive, absorbent, anticaking agent, anticoagulant, base, bulking agent, coating agent, colour additive, diluent, filler, flow enhancer, glidant, lubricant, opacifying agent, or slip modifier (NHPID [modified 2019]). Talc is listed in the Diaper Rash Products Monograph as a permitted medicinal ingredient in diaper rash products in concentrations ranging from 45% to 100% (Health Canada 2018). However, there are no diaper rash products listed in the Licensed Natural Health Products Database (LNHPD) containing talc as a medicinal ingredient (LNHPD [modified 2018]). Talc is permitted as a medicinal ingredient in the Traditional Chinese Medicine Ingredients monograph (Health Canada 2015). Talc is listed in the LNHPD as being present as a medicinal or non-medicinal ingredient in approximately 2100 currently licensed NHPs in Canada (LNHPD [modified 2018]).

Based on notifications submitted from 2017 to 2020 under the *Cosmetic Regulations* to Health Canada, talc is an ingredient in approximately 7750 cosmetic products in Canada (personal communication, emails from the Consumer and Hazardous Products Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 27, 2020; unreferenced). Talc is considered a restricted ingredient in cosmetics.⁹ The Cosmetic Ingredient Hotlist entry for cosmetics

⁷ While not defined under the Food and Drugs Act (FDA), incidental additives may be regarded, for administrative purposes, as those substances that are used in food processing plants and that may potentially become adventitious residues in foods (e.g., cleaners, sanitizers).

⁸ Self-care products are products available for purchase without a prescription from a doctor and fall into one of three broad categories: cosmetics, natural health products, and non-prescription drugs.

⁹ Talc is described as a restricted ingredient on the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply the Hotlist), an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* (FDA) or may contravene one or more provisions of the

containing talc in powder form intended to be used on infants and children indicates that product labels should display statements to the effect of “keep out of reach of children” and “keep powder away from child’s face to avoid inhalation which can cause breathing problems.” As per the Cosmetic Regulations, the label of a cosmetic that presents an avoidable hazard must include directions for safe use, in both English and French.

High-purity talc is used in self-care products, while lower-grade talc is used in the many commercial applications mentioned above. Approximately 2% to 4% of the talc produced and sold in North America is used in cosmetics (Kogel et al. 2006; USGS 2020).

Condoms and medical gloves are regulated as Class II medical devices in Canada under the *Medical Devices Regulations* and may be sources of exposure if talc is present as a dry lubricant. However, internationally, there was a shift from the use of talc as a dry lubricant on medical patient examination gloves to cornstarch in the 1980s (Lundberg et al. 1997). In 2016, the U.S. FDA banned powdered patient examination gloves (United States 2016). There has also been a shift from the use of talc as a dry lubricant in condoms, and starch is more commonly used (Douglas et al. 1998). A 1998 study did not find talc in a small survey of condoms tested in Canada (Douglas et al. 1998). Condom standards and specifications require the use of dry lubricants, if present, to be bioabsorbable, such as starch and calcium carbonate; talc should not be used (Douglas et al. 1998; WHO, UNFPA, FHI 2013).

5. Environmental fate and behaviour

5.1 Environmental persistence

Talc is considered persistent because it is an insoluble mineral with environmental stability on geological timescales (Bricker et al. 1973). Persistence was also evaluated using read-across with synthetic amorphous silicates. Silica and silicates are expected to be resistant to photodegradation, chemical degradation and biodegradation due to their inorganic structure and the high stability of Si-O bonds (OECD 2004).

5.2 Potential for bioaccumulation

Bioaccumulation potential data for talc are lacking for ecological receptors. However, due to talc’s low water solubility and absence of lipophilicity, bioaccumulation of talc in ecological receptors is not anticipated. Talc may be retained in lung tissue of mammals (Danish EPA 2016), but inhalation of significant quantities of talc is an unlikely exposure

Cosmetic Regulations. Section 16 of the FDA states that “no person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user.” In addition, the Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the FDA (Health Canada [modified 2018]).

scenario for ecological receptors. Bioaccumulation potential was further evaluated using read-across with synthetic amorphous silicates. Silica can be actively accumulated by some organisms (e.g., some terrestrial plants and diatoms). However, the bioaccumulation potential of silica and silicates is low because of the capacity of organisms to excrete SiO_2 components and the absence of lipophilicity in these substances (OECD 2004). There is currently no evidence to suggest that silica and silicates or talc bioaccumulate to harmful levels in the environment.

6. Potential to cause ecological harm

6.1 Characterization of ecological risk

The ecological risk of talc was characterized using the Ecological Risk Classification of Inorganic Substances (ERC-I) (ECCC 2018), which is a risk-based approach that employs multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard characterization in ERC-I included a survey of published PNECs and water quality guidelines from domestic and international assessments. When no suitable existing PNEC or water quality guideline was found, hazard endpoint data were collected and, depending on data availability, either a species sensitivity distribution (SSD) or an assessment factor (AF) approach was taken to derive a new PNEC value. In the case of talc, hazard endpoint data from the Organisation for Economic Co-operation and Development Screening Information Dataset (SIDS) for synthetic amorphous silicates (OECD 2004) were identified for read-across (ECCC, HC 2017) and an AF approach was used to derive a PNEC value of 40 mg/L (ECCC 2018).

Exposure profiling in ERC-I considered two approaches: predictive modelling using a generic near-field exposure model and an analysis of measured concentrations collected by federal and provincial water quality monitoring programs. The generic near-field exposure model used input data, when available, from the National Pollutant Release Inventory (NPRI), information submitted in response to CEPA section 71 surveys, international trade data from the Canada Border Services Agency (CBSA), and third-party market research reports to generate PECs. For talc, only information submitted in response to a CEPA section 71 survey and international trade data from CBSA were available to generate PECs. Engineered nanomaterials containing talc are not explicitly considered in the exposure scenarios of this assessment but may have been included in the quantities reported.

Modelled PECs were compared to the PNEC, and statistical metrics that consider both the frequency and magnitude of exceedances were computed and compared to decision criteria to classify the potential for ecological risk (ECCC 2018). The results are summarized in Table 6-1. Based on the outcome of the ERC-I analysis, talc is considered unlikely to be causing ecological harm.

Table 6-1. Ecological risk classification of inorganics results for talc

Monitoring (total/extractable)	Monitoring (dissolved)	Modelling (s.71 of CEPA)	Modelling (NPRI)	Modelling (CBSA)	Overall ERC-I score
NA	NA	Low	NA	Low	Low

Abbreviations: NA, not available.

7. Potential to cause harm to human health

7.1 Health effects assessment

Talc was previously reviewed internationally by the IARC, and an IARC monograph is available (IARC 2010). Additionally, talc was reviewed by the U.S. EPA, JECFA, and Danish EPA (U.S. EPA 1992; JECFA 2006; Danish EPA 2016). Talc was also assessed by the MAK-Commission in Germany and by the CIR Expert Panel (MAK-Commission 2012, CIR 2013; Fiume et al. 2015).

As part of a weight of evidence assessment (Health Canada [modified 2017]), a literature search was conducted from January 2015 (the year prior to the most recent assessment (the 2016 Danish EPA review)) to September 2020, to identify additional studies of adequate quality and relevance for inclusion in the screening assessment. No additional health effects studies that could impact the risk characterization (i.e., result in different critical endpoints or lower points of departure than those stated in existing reviews and assessments) for oral, dermal, or inhalation exposures were identified. For perineal exposures, recently published literature was identified and considered in the assessment.

The health effects of talc are outlined by route of exposure in the following sections.

Toxicokinetics

Talc is poorly absorbed via the oral route of exposure. Following gavage administration of radiolabelled talc to rodents, the majority of the administered dose (AD) remained in the gastrointestinal (GI) tract and was eliminated in the feces ($\geq 95.8\%$ of AD) within 3 to 4 days of dosing (Wehner et al. 1977a; Phillips et al. 1978). Less than 2% of the AD was recovered in the urine; however, this was mainly attributed to contamination from feces during collection, with true absorption and urinary clearance expected to be even lower. At 24 hours post administration, less than 2% of the AD remained in the carcass of hamsters; no radioactivity was detected in mouse carcasses at this time point. In rats and guinea pigs, only trace amounts of radioactivity remained in the GI tract at 10 days post administration.

As an insoluble solid, talc is not expected to be absorbed when applied to healthy and intact skin. There are no indications of dermal absorption following talc exposure (MAK-

Commission 2012). According to a review by the MAK-Commission (2012), there are no indications of metabolism via typical degradation pathways, independent of route of exposure, from which toxicologically relevant degradation products may develop.

In general, inhaled particles 5 to 10 μm are eliminated from the respiratory tract via mucociliary clearance, while smaller particles ($< 5 \mu\text{m}$) can be transported to the smaller airways and deposit deep in the alveolar region of the lung, relying on alveolar macrophage mediated clearance (Leikauf 2013). The shape and surface area will also influence lung deposition and clearance (Steiling 2018). In female Syrian hamsters that were administered aerosolized neutron-activated cosmetic talc by nose-only inhalation at concentrations of 40 to 75 mg/m^3 (95% pure; median mass aerodynamic diameter (MMAD) 6.4 to 6.9 μm) over a 2-hour exposure period, 6% to 8% of the AD was deposited into the alveoli (Wehner et al. 1977b). The biological half-life following a single exposure was estimated to be between 7 and 10 days, with complete alveolar clearance after 4 months. There was no translocation of talc from the respiratory tract to the liver, kidneys, ovaries, or other parts of the body. Lung clearance was noted to be longer in other species. The Danish EPA (2016) remarked that talc, including the respirable fraction, is not absorbed following inhalation, but is retained in the lung tissue. They further stated that lung burden correlates to exposure concentrations, with clearance of talc from the lung impaired to a greater extent with increasing exposure concentrations. Pulmonary retention half-lives for talc particles in the lungs of rodents from the U. S. National Toxicology Program (NTP) chronic inhalation studies were estimated to be as long as 300 days in rats and 1000 days in mice (revisit of NTP data by Oberdorster 1995). Other authors (Pickrell 1989; MAK-Commission 2012) noted similar findings indicating that with repeat exposures, alveolar clearance in rats may be impaired at concentrations of only 2 $\text{mg talc}/\text{m}^3$ air.

Limited information is available for the toxicokinetics of talc particles following perineal exposure. The available information is summarized in the section on *Perineal exposure to talc* below, under *Mode of action*.

Health effects

Oral route of exposure

Talc was considered to be of low concern with respect to human health via oral exposure. Repeated-dose testing via oral exposure to talc in animals did not produce any adverse effects with respect to repeated-dose toxicity, carcinogenicity, reproductive/developmental toxicity, or mutagenicity (Gibel et al. 1976; Wagner et al. 1977; NTP 1993; IARC 2010; Danish EPA 2016).

Talc has not been shown to produce adverse effects when ingested orally. As a result, the use of talc in various tablet formulations was not considered hazardous via the ingestion route (Hollinger 1990; U.S. EPA 1992).

In addition, the Commission of the European Communities' report on Dietary Food Additive Intake in the European Union identified talc as having an acceptable daily intake (ADI) of "not-specified." The JECFA has also assessed talc and assigned an ADI of "not specified" due to the lack of toxicity from oral exposure. The substance was considered not to be a hazard to human health at oral intake levels noted in total diet surveys, which represents the main sources of oral exposure for this substance (IARC 1987; EU [modified 2001]). Furthermore, talc is considered "generally recognized as safe" for specific uses in food packaging in the United States (U.S. FDA GRAS list) without being subject to pre-market approval requirements (U.S. FDA 2019a, b).

Dermal route of exposure

There are limited data available on repeated-dose studies via dermal exposures to talc (Danish EPA 2016). In the available literature, only one repeated-dose dermal toxicity study was identified (Wadaan 2009). Severe limitations were noted for this study, including a lack of information on the test substance and the dose applied, as well as a lack of detail regarding the test animals. Skin dryness and erosion were noted; however, application sites were shaved, indicating that talc may have been applied to broken skin. Additionally, there were no indications of irritation, sensitization, or dermal absorption following exposure to unabraded and/or non-diseased skin (MAK-Commission 2012). A 3-day occlusive application of pharmaceutical-grade talc did not show any signs of irritation in five human volunteers (Frosch and Kligman 1976, as reported in MAK-Commission 2012).

Case reports, however, do indicate that the application of talc to diseased or broken skin can cause the formation of granulomas, particularly if the talc particles have a large diameter (MAK-Commission 2012; CIR 2013; Fiume et al. 2015). In addition, granulomas have been observed in the umbilical regions of infants, in the testes, on the vocal cords, in the urinary tract, and during phlebectomies following contact with talc-powdered surgical gloves (Ramelet 1991, as reported in MAK-Commission 2012; Simsek et al. 1992, as reported in MAK-Commission 2012). As a result, the CIR concluded that "talc should not be used on skin where the epidermal barrier is removed or on skin that has greater than first degree burns."

Although dermal contact with talc is expected from the use of various products available to consumers, talc is a chemically inert, solid powder that is insoluble in water (Table 3-1). As a result, it does not penetrate intact skin, and therefore systemic absorption through the skin is not expected. Consistent with other international regulatory and advisory bodies (Danish EPA, U.S. EPA, MAK-Commission, U.S. FDA, and JECFA), a dermal health effects endpoint has not been identified for talc.

Inhalation route of exposure

Human studies

Epidemiological data for workers exposed to talc via inhalation have been reviewed and discussed by the U.S. EPA (1992), IARC (2010), MAK-Commission (2012) and Danish EPA (2016).

The Danish EPA (2016) noted that talc is not absorbed via inhalation. Rather, particles are retained in the lung, and lung burden is reported to increase proportionally with exposure concentration and frequency. The Danish EPA (2016) detailed epidemiological data that noted mortalities in workers due to lung diseases following exposures to talc. However, it was stated that there was no increase in the lung cancer rate in talc millers in the absence of exposure to carcinogens. A recent meta-analysis by Chang et al. (2017) reported a positive association with lung cancer in workers exposed to talc. However, co-exposure to other hazardous materials in the workplace and smoking were not adequately accounted for.

The chronic inhalation of talc leads to lung function disorders and fibrotic changes in humans. Since talc particles are persistent, they have the potential to accumulate in human lung tissue, which may lead to both an impairment of the self-cleaning mechanism of the lungs (reduced ability to fight infections) and inflammatory changes and fibrosis. Talc particles may be enclosed in a foreign-body granuloma as the result of an inflammatory reaction. The mobility of the macrophages is restricted by phagocytized talc particles, leading to changes in the function of these cells and subsequently to chronic inflammatory reactions (Gibbs et al. 1992).

In humans, there are reports of pure talc-induced pneumoconiosis or talcosis following repeated inhalation exposure to talc. Talcosis has been reported to occur in miners, millers, rubber workers, and other occupational groups exposed to talc without asbestos or silica (Fine 1976; Vallyathan and Craighead 1981; Feigin 1986; Gibbs et al. 1992; Wild et al. 1995; Akira et al. 2007) after long term exposures at air concentrations estimated to be as low as $< 1 \text{ mg/m}^3$. The Danish EPA relied upon a more recent longitudinal survey of French and Austrian talc workers (Wild et al. 2008) in which the prevalence of small radiological opacities and decreases in lung function parameters were related to cumulative exposure at study inclusion. Previous samples taken from the French cohort (Wild et al. 1995) indicated a correlation between talc exposures and lung effects. However, as the follow-up study progressed, talc exposure did not produce additional changes. It should be noted that confidence intervals for exposures within the study were large, indicating high variability in the data. The mean estimated talc dust concentration during the mean duration of follow-up (14.5 years) was 1.46 mg/m^3 (Wild et al. 2008).

With respect to non-occupational human exposures, cases have been reported of individuals exposed to talc (from acute to prolonged exposures) who seek treatment for non-specific complaints, including progressive exertional dyspnea and dry or productive cough, with indications of lung lesions (Marchiori et al. 2010; Frank and Jorge 2011). Talcosis has been shown to occur in children and adults, with symptoms that developed shortly after acute to short-term exposure or up to 10 years later (Patarino et al. 2010;

Shakoor et al. 2011). Inhalation of talc has been known to cause pulmonary effects, even following single acute exposures, as reported in a 10-year-old child who had a history of a single exposure to talc at two years of age (Cruthirds et al. 1977). Another case report detailed a 7-year-old child who developed asthma and reduced lung function after a single exposure event (Gould and Barnardo 1972). Additionally, a 52-year-old woman who used baby talcum powder regularly, at least twice a day (usually after bathing for personal hygiene and habitually applying it to her bed sheets nightly) for 20 years, was reported to have dyspnea, along with a persistent dry cough and unintentional rapid weight loss. A radiographic exam noted evidence of interstitial lung disease with fibrosis (Frank and Jorge 2011).

Other relevant case reports include that of a 55-year-old woman, occupationally exposed to talc as a dusting agent on packed rubber balls from 1958 to 1968, who was reported to develop dyspnea during the first 5 years after exposure (Tukiainen et al. 1984), and a 62-year-old woman occupationally exposed to talc for 5 years who was reported to have progressive lung fibrosis for more than 40 years (Gysbrechts et al. 1998).

Animal studies

Similar to what has been observed in humans, inhalation of talc in animals may elicit inflammation and lead to lung disease (Sato et al. 2020). Inhalation studies conducted with talc in animals have been cited and reviewed by the U.S. EPA (1992), IARC (2010), MAK-Commission (2012) and Danish EPA (2016) and are summarized in this section. A literature search was conducted from the year prior to the most recent assessment to September 2020, and no studies were identified that produced lower points of departure or different critical endpoints than the studies summarized in this section. In addition, a number of studies were noted to have significant limitations and are not considered further in this assessment.

In a repeated-exposure study conducted by the U.S. NTP, groups of F334/N rats were exposed to aerosolized talc (MMAD 2.7 to 3.2 μm ; Geometric Standard Deviation (GSD) 1.9) via the inhalation route of exposure. Test animals were exposed (whole-body) for 6 hours per day, 5 days per week, for up to 113 weeks (males) or up to 122 weeks (females) to aerosols of 0, 6, or 18 mg/m^3 talc (49 or 50 males per group, 50 females per group) (NTP 1993). Mean body weights of rats exposed to 18 mg/m^3 talc were slightly lower than those of controls after week 65. No clinical observations were attributed to talc exposure. Absolute and relative lung weights of male and female rats exposed to 18 mg/m^3 talc were significantly greater than those of controls. Inhalation exposure produced a spectrum of inflammatory, reparative, and proliferative processes in the lungs. Granulomatous inflammation, which was evident as early as 6 months (first histopathological examination), occurred in nearly all exposed rats, and the severity increased with exposure duration and concentration. Hyperplasia of the alveolar epithelium and interstitial fibrosis occurred in or near the foci of inflammation in many exposed rats, while squamous metaplasia of the alveolar epithelium and squamous

cysts were also occasionally seen. Accumulations of macrophages (histiocytes), most containing talc particles, were found in the peribronchial lymphoid tissue of the lung and in the bronchial and mediastinal lymph nodes. In exposed male and female rats, there was a concentration-related impairment of respiratory function, beginning at 11 months, which increased in severity with increasing exposure duration. The impairment was characterized by reductions in lung volume (total lung capacity, vital capacity, and forced vital capacity), lung compliance, gas exchange efficiency (carbon monoxide diffusing capacity), and non-uniform intrapulmonary gas distribution (NTP 1993). Based on these results, a lowest observed adverse effect concentration (LOAEC) of 6 mg/m³ was established for non-cancer lung effects.

In female rats, at 18 mg/m³ talc, the incidences of alveolar/bronchiolar adenoma, carcinoma, and adenoma or carcinoma (combined) were significantly greater than those of controls (NTP 1993). The incidences of lung neoplasms in exposed male rats were similar to those in controls. Adrenal medulla pheochromocytomas (benign, malignant, or complex [combined]) occurred with a significant positive trend in male and female rats, and the incidences in the 18 mg/m³ talc groups were significantly greater than those of controls (NTP 1993).

The NTP (1993) concluded that there was some evidence of carcinogenic activity of talc in male rats on the basis of an increased incidence of benign or malignant pheochromocytomas of the adrenal gland. They also concluded that there was clear evidence of carcinogenic activity of talc in female rats on the basis of increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.

In a subsequent symposium, experts from the NTP, along with academic, industry, and government experts, re-examined the results of the chronic inhalation studies. The general consensus from the expert panel was that the highest dose tested (18 mg/m³) exceeded the maximum tolerated dose (MTD) and, for that reason, the neoplasms noted were considered not relevant to human health risk assessment (Carr 1995). A similar conclusion was reported by Warheit et al. (2016). The Danish EPA (2016) and the MAK-Commission attributed lung tumours in female rats to the general particle effect of granular biopersistent dusts, which manifests as lung tumours in rodents only, an effect that would not be specific to the talc particles. They also attributed the pheochromocytomas to an increase in cell proliferation due to hypoxia, which was considered to be a high-dose effect (MAK-Commission 2012).

In another chronic NTP study, B6C3F1 mice were exposed to aerosolized talc via the inhalation route (NTP 1993). Test animals (47 to 49 males per group, 48 to 50 females per group) were exposed (whole-body) for 6 hours per day, 5 days per week, for up to 104 weeks to aerosols of 0, 6, or 18 mg/m³ talc (MMAD 3.3 to 3.6 µm; GSD 1.9 to 2.0). Survival and final mean body weights of male and female mice exposed to talc were similar to those of controls. Animals appeared normal in cage-side observations conducted throughout the study. Chronic active inflammation and the accumulation of

macrophages, which contained talc, were observed in the lungs of mice exposed to both concentrations of talc. In contrast to rats, hyperplasia of the alveolar epithelium, squamous metaplasia, or interstitial fibrosis were not associated with the inflammatory response in mice, and the incidences of lung neoplasms in exposed and control groups of mice were similar. Accumulations of macrophages (histiocytes) containing talc particles were also present in the bronchial lymph node. The critical effect level and corresponding health effects endpoint was a LOAEC of 6 mg/m³ for non-cancer lung effects (NTP 1993).

Doses used in its chronic studies were selected by the NTP on the basis of the results of a 4-week inhalation study (1993) in which rats and mice were exposed to talc at 0, 2, 6, or 18 mg/m³ for 6 hours a day, 5 days a week. Lung burden was noted to be increased in a dose-dependent manner, with overload noted by the study authors at 6 and 18 mg/m³ in rats but not at any dose in mice.

In a review of the NTP studies, Oberdorster (1995) revisited the lung deposition data and particle accumulation kinetics in the lungs of rats and mice, demonstrating that impaired clearance and lung overload was reached at 6 mg/m³ and above, for both sexes, in rats and mice. A recent review by Bevan et al. (2018) explores the issue of lung overload and lung cancer associated with toxicity testing of poorly soluble particles in rodents. They concluded that while the evidence suggests that the rat lung model is unreliable as a predictor for human lung cancer risk associated with these substances, it is a sensitive model for detecting various threshold inflammatory markers, with utility for use in non-neoplastic risk assessment.

A no observed adverse effect concentration (NOAEC) of 2 mg/m³ was derived from the NTP 4-week study, on the basis of increased lung burden and impaired clearance at a LOAEC of 6 mg/m³ following 4 weeks of dosing. At the same concentration (6 mg/m³), granulomatous inflammation and alveolar epithelial hyperplasia were noted at a 6-month interim sacrifice in the chronic rat inhalation study, and interstitial fibrosis and impaired lung function were noted in some animals at 11 months. As noted previously, following a single exposure in rats, the biological half-life for ciliary clearance was between 7 and 10 days, indicating that previous exposure would not have cleared prior to subsequent exposures, leading to a build-up in lung tissue. In a re-examination of the NTP lung burden data, Oberdorster (1995) estimated that lung retention half-lives of talc particles were between 250 and 300 days in the rat chronic study.

The Danish EPA (2016) established a health-based quality criterion for ambient air (QC_{air})¹⁰ of 0.004 mg/m³, based on both animal and human data. The LOAEC of 6 mg/m³ from the chronic NTP studies (mice and rats) and the NOAEC of 1.5 mg/m³ for

¹⁰ The health-based quality criterion in ambient air (QC_{air}) is a reference concentration that refers to the maximum permissible contribution to air from industrial sources.

talc-induced non-cancer lung effects in the longitudinal survey of French and Austrian talc workers (Wild et al. 2008) were each considered as relevant points of departure by the Danish EPA. After incorporating uncertainty factors (250 for the animal endpoint and 100 for the human endpoint) to address inherent uncertainties within the database (e.g., limitations in the human and animal data, variability within the human population), a QC_{air} of 0.004 mg/m³ was established by the Danish EPA.

Although human occupational studies and case studies are available, these studies do not provide accurate measures of exposure for use in establishing points of departure for quantitative risk characterization. However, human studies do note a similar range of lung effects and disease as animal models. Results from the above-noted animal studies were therefore selected for the non-cancer risk characterization. On the basis of the NTP studies with rats and mice exposed to cosmetic-grade talc, a NOAEC of 2 mg/m³ for non-cancer lung effects is considered to be appropriate for the inhalation route of exposure for short- or long-term use. Given the long half-life and slow lung clearance of talc from the lungs, even episodic exposures would be expected to increase lung load. The NOAEC of 2 mg/m³ was derived from a study in which animals were exposed on an intermittent basis (6 hours per day, 5 days a week). It was adjusted to a concentration that represents continuous exposure, using the U.S. EPA guidance on inhalation risk assessment¹¹ (U.S. EPA 1994, 2009). The adjusted NOAEC for non-cancer effects is 0.36 mg/m³. This adjustment is considered appropriate to apply when the available data indicate that both concentration and time (c x t), not concentration alone, are likely to affect the toxicity observed.

Perineal exposure to talc

In 2006, the IARC classified perineal use of talc-based body powder as “possibly carcinogenic to humans” (Group 2B) on the basis of limited evidence in humans. The IARC reported that “many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out” (IARC 2010).

In 2014, in response to citizen petitions, the U.S. FDA reviewed the available scientific information and did not find that the data presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer. However, the U.S. FDA recognized that a possible association may exist. In their correspondence to

¹¹ This adjustment was made according to guidance and equations outlined in the U.S. EPA Supplemental Guidance for Inhalation Risk Assessment (U.S. EPA 2009) and the U.S. EPA Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA 1994). Adjustment of duration to a continuous exposure scenario is done through the use of Equation 1 from U.S. EPA 2009, i.e., $NOAEC[ADJ] = E \times D \times W$, where the $NOAEC[ADJ]$ (mg/m³) = the no-observed adverse effect level (NOAEC) adjusted for the duration of the experimental regimen; E (mg/m³) = the NOAEC or analogous exposure level observed in the experimental study; D (h/h) = the number of hours exposed/24 hours; and W (days/days) = the number of days of exposure/7 days. The $NOAEC[ADJ] = 2 \text{ mg/m}^3 \times 6\text{h}/24\text{h} \times 5\text{d}/7\text{d} = 0.36 \text{ mg/m}^3$.

the petitioner they note; “while the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as [you] are seeking” (U.S. FDA 2014).

The National Cancer Institute’s Physician Data Query for Health Care Professionals (NCI 2019) states that “[t]he weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer.”

The CIR Expert Panel (2013) determined that there is no causative relationship between cosmetic use of talc in the perineal area and ovarian cancer and that talc is safe in the practices of use and concentration described in the CIR safety assessment. Issues noted by the CIR included a lack of consistent statistically significant positive associations across all studies; small risk ratio estimates; a failure to rule out other plausible explanations such as bias, confounders, and exposure misclassifications; and a lack of evidence from studies of occupational exposures and animal bioassays (CIR 2013; Fiume et al. 2015).

Several publications became available after the IARC, U.S. FDA and CIR assessments and suggest that the relationship between perineal talc exposure and ovarian cancer is causal (Narod 2016; Penninkilampi and Eslick 2018; McTiernan 2019; Taher et al. 2019). Other authors do not indicate a causal relationship (Huncharek and Muscat 2011; Berge et al. 2018; Goodman et al. 2020; Johnson & Johnson Consumer, Inc. 2020).

The etiology of most ovarian tumours has not been well established, and ovarian cancer is a relatively rare disease (NASEM 2016; AICR 2020; CTFPHC 2020; NCI-SEER 2020). There are a number of different tumour types with characteristic histologic features, distinctive molecular signatures, and disease trajectories. Moreover, these tumours are heterogeneous and can arise from different tissues of the female reproductive tract, including the fallopian tube epithelium (Piek et al. 2001; Piek et al. 2003; Finch et al. 2006; Kindelberger et al. 2007; Przybycin et al. 2010; Morrison et al. 2015; NASEM 2016). Ovarian tumours can be grouped into categories (e.g., epithelial ovarian cancer, germ cell tumours, gonadal stromal tumours, metastatic neoplasms). Epithelial ovarian cancers are often designated as Type I or Type II, with further subdivision within each type. Type I tumours have characteristics quite distinct from Type II tumours, and research supports that they have different molecular pathways and may not be ovarian in origin (Kurman and Shih 2011; Seidman et al. 2011; Kuhn et al. 2012; Kurman and Shih 2016).

Tumour subtypes are one of the many subgroup analyses conducted in several of the epidemiology studies and reviews. However, there was very little consistency in whether, or how, these subgroup analyses were conducted across the available studies, thereby leaving the analyses limited and likely underpowered (low sample sizes). Furthermore, there is considerable uncertainty for how subgroup data should be

examined, in particular, for the tumour subtypes. Therefore, subgroup analyses will not be further examined in this assessment.

Mode of action

The possibility that talc could migrate to the ovaries from perineal use was postulated following work by Henderson et al. (1971). In terms of disposition, talc particles were identified in 10 of 13 human ovarian tumours and 12 of 21 cervical tumours but were also found in 5 of 12 “normal” ovarian tissues removed from patients with breast cancer (Henderson et al. 1971). A follow-up study was conducted in order to control for talc contamination (e.g., from surgeons’ gloves) and again talc was found in all samples: three normal ovaries, three cystic ovaries and three adenocarcinomas (Henderson et al. 1979). There was no information provided on the patients in these studies with respect to history of perineal talc use.

In a separate study, ovaries from 24 patients undergoing incidental oophorectomy were examined; 12 women reported frequent perineal talc use (ever-users) and the other 12 women were non-users. Talc particles were detected in all 24 cases (both ever- and non-users) and there was no relation found between reported levels of exposure and talc particle counts in ovaries (Heller et al. 1996). Wehner (2002) attributed the talc in the non-users to (a) possible sample contamination, because some studies using negative controls resulted in particle counts similar to the test sample; and/or (b) possible false positives due to the use of a single radioactive tracer. Heller et al. (1996) hypothesized that talc use during diapering could also contribute to the ovarian particle burden.

A case report has been described of a woman with advanced ovarian serous carcinoma known to have used talc in her genital area daily for 30 years. Talc was shown to be present in macrophages within pelvic lymph node tissue. It was therefore unlikely to be due to surface contamination and likely was caused by talc migration up the reproductive tract to the ovaries (Cramer et al. 2007; Campion et al. 2018). In a more recent study, McDonald et al. (2019b) aimed to differentiate the presence of talc in pelvic lymph nodes due to talc exposure versus contamination. The study showed that the methods used for assessment and quantification of talc can drastically affect the findings. Digestion of the tissue sample may be more greatly influenced by contamination than using *in situ* scanning electron microscopy/energy dispersive X-ray analysis (*in situ* SEM/EDX). In one experiment, nodes in 22 patients with various types of ovarian tumours were examined (45% had used talc in their genital areas and 73% had used it as a body powder) by digestion and regular SEM/EDX. A measure of surface contamination (presence of material along specimen edge) was also estimated for each sample. Overall, genital talc users had higher talc counts than non-users, but the association was of borderline significance. However, after adjusting for surface contamination, talc burden in nodes correlated strongly with genital talc use. In a second experiment, 19 lymph node specimens from 10 carcinoma cases (talc exposure unknown) were assessed by *in situ* SEM/EDX without digestion, which allowed for

distinction of interior tissue versus exterior surfaces. This portion of the study confirmed talc as surface contamination particles (McDonald et al. 2019b).

Migration or retrograde movement of talc particles from the vagina to the ovaries has been identified as a plausible explanation of the above findings (i.e., talc particles in the upper reproductive tract) (Henderson et al. 1986; Heller et al. 1996; Cramer et al. 2007). The U.S. FDA (2014) stated “[w]hile there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable.” Schildkraut et al. (2016) suggested that talc particles might also translocate to the ovaries following inhalation exposure to fine talc particles. However, these findings were not evident in the hamster inhalation study summarized above under *Toxicokinetics* (Wehner et al. 1977b). Some authors have noted the idea that the uterus and fallopian tubes act as a peristaltic pump to help retrograde movement of sperm (Zervomanolakis et al. 2007), which could also help transfer particles up the reproductive tract. Studies specifically assessing potential movement of talc particles through the human body were not identified in the literature. The limited information that was available reported mixed results; however, the possibility of translocation of fine and ultrafine particulate matter, in general, has been noted (Peters et al. 2006).

A suspension of talc (100 mg/ml in saline) was introduced into the cervical canal of female rats (n = 8). Half of the rats were sacrificed 5 days later and the remaining rats went on to receive up to four further instillations. A similar procedure was conducted on an additional 12 rats; however, the suspension was deposited into the vagina and animals were sacrificed after 24 hours, 48 hours or 4 days. Talc particles were detected in the ovaries of all the rats that received intrauterine instillations as well as the rats that received intravaginal treatment killed after 4 days. There was no talc detected in the control rats, nor in the rats receiving intravaginal treatment that were killed at 24 hours or 48 hours (Henderson et al. 1986). Conversely, in other species, no translocation of talc into the ovaries was detected after single or multiple intravaginal applications. Female rabbits were given a single dose (n = 3) or six daily doses (n = 3) of a radiolabelled talc suspension intravaginally and killed 3 days following the last dose. Radioactivity was detected at the site of administration in all rabbits, and a small amount was found in the cervix and fallopian/uterine tubes in the repeated dose rabbits; however, no radioactivity was detected in the ovaries (Phillips et al. 1978). Similarly, in monkeys receiving 30 applications daily over consecutive work days of neutron-activated talc in saline deposited in the posterior vaginal fornix, samples from the vagina and cervix contained talc, whereas samples from the uterus or ovaries did not (Wehner et al. 1986). This confirmed results from the pilot study in an earlier paper with fewer monkeys and only a single dose, in which no measurable talc was found deposited in the uterine cavity or further up the reproductive tract (Wehner et al. 1985).

Translocation of other inert particles, similar in size to talc, has also been studied in humans and animals. Retrograde migration was studied in rabbits administered a lubricant powder intravaginally. There were no overall statistically significant differences

between the control and experimental animals; however, some measured parameters (large particles from peritoneal fluid cell pellets and small particles in cervix) did show significant differences and indicated that the possibility of retrograde migration could not be excluded (Edelstam et al. 1997). A subsequent study in humans was conducted where patients (n = 12 to 17) undergoing elective hysterectomy were examined either with powdered gloves or powder-free gloves at 1- or 4-days pre-operatively. For those examined 1-day pre-operatively, statistically significant increases in large and small starch particles were found in the cervix, uterus and tubes. At 4-days pre-operatively, increases were only significant in the cervix and uterus. Particles were however found in three control patients, and two of the test subjects had no particles detected (Sjosten et al. 2004).

Three human patients undergoing a scheduled hysterectomy had a suspension of carbon particles deposited in the posterior fornix of the vagina after general anesthesia was induced. Carbon particles were recovered from the fallopian tubes of two of the three women approximately 30 minutes following administration. No carbon particles were found in the fallopian tubes of the third patient 20 minutes after administration. There were no control patients in this study (Egli and Newton 1961). De Boer (1972) conducted a similar experiment using a colloidal suspension of carbon placed into patients about to undergo abdominal surgery. Carbon material was found in the fallopian tubes of more than 50% of the patients when the suspension was placed in the uterine cavity but only once in 37 observations when it was placed in the vagina. Venter and Iturralde (1979) reported a study where radiolabelled human albumin microspheres were deposited in the posterior fornices of 24 patients admitted to hospital for elective gynecological surgeries. Sixteen had radioactive tracer in the uterus, fallopian tubes and/or ovaries, five were negative and the remaining three were excluded due to technical error. Technetium-labelled albumin microspheres were also used by Kunz et al. (1996) and Kissler et al. (2004). A suspension was placed into the posterior vaginal fornix of 64 women during the early, mid- and late follicular phases of the cycle. Ascension of the microspheres to the tubes occurred rapidly and quantitatively increased with progression of the follicular phase (Kunz et al. 1996). Kissler et al. (2004) found that uterine contractility was influenced by estradiol levels. The rate and direction of contractions varies throughout the cycle of nonpregnant humans. Small and frequent contractions in retrograde direction occur from the end of menstruation until the late proliferative phase; during menstruation, the direction reverses.

With respect to talc and induction of tumours, local chronic irritation leading to an inflammatory response is one possible mechanism of tumour progression that is frequently hypothesized in the literature (Muscat and Huncharek 2008; Penninkilampi and Eslick 2018; Taher et al. 2019; O'Brien et al. 2020). An inflammatory response associated with talc has been clearly demonstrated in lung tissue (Sato et al. 2020) and utilized clinically in pleurodesis (Van den Heuvel et al. 1998; Genofre et al. 2007; Arellano-Orden et al. 2013), and there is support for an association of inflammation and increased risk of ovarian cancer (Cheng et al. 2000; Yan et al. 2006; NASEM 2016; Rasmussen et al. 2017). Persistent indications of inflammation (including C-reactive

protein, tumour necrosis factor, and other inflammatory markers) are detected in the blood of women prior to a diagnosis of ovarian tumours (Trabert et al. 2014), while other inflammatory markers have been found in the blood of women who used talc products daily for more than 20 years (Williams et al. 2014). Zeng et al. (2016) performed a meta-analysis of eight epidemiology studies and determined that elevated levels of C-reactive protein was associated with a significantly increased risk of ovarian cancer. In an animal study (summarized below), Keskin et al. (2009) measured an increase in the number of inflammatory cells in all genital tissues of rats intravaginally exposed to talc for 3 months. It should be noted however that the rats also developed infections over the course of the study which could have led to the increase in inflammatory cells.

A recent study (Fletcher et al. 2019) was conducted to determine the effect of talc on the expression of enzymes and markers associated with inflammation, and the effect on cell proliferation and apoptosis in normal cells compared to epithelial ovarian cancer cells was also examined. There was a dose-dependent significant increase in key prooxidants and a decrease in key antioxidant enzymes in all talc-treated cells compared to controls. It was found that talc exposure induced specific point mutations that are known to alter the activity of some of these enzymes. There was an increase in inflammation as determined by a significant increase in the tumour marker CA-125. And lastly, talc-exposed cells had significantly induced cell proliferation and decreased apoptosis. Such changes (shifts in key redox and inflammatory markers, enhanced cell proliferation and apoptosis inhibition) are all hallmarks of ovarian cancer (Fletcher et al. 2019) and support the hypothesis that talc exposure may lead to ovarian cancer through inflammatory mechanisms.

In another recent study (McDonald et al. 2019a), five cases (patients with ovarian cancer and a history of perineal talc use) and six controls (patients with ovarian cancer and no genital exposure to talc) were assessed. Surgically resected pelvic tissues (ovary, fallopian tube, cervix/uterus, lymph node) were examined by polarized light microscopy (PLM), SEM and EDX. Talc was found in at least two and up to four pelvic organ sites distant from the perineum in all five of the cases, yielding an aggregate total of 503 talc particles for the five cases. This can be compared to the four total talc particles found in the controls (two in the ovary of one patient and two in the fallopian tube of another patient). The presence of asbestos fibres was also investigated and nothing above the level of detection was measured in any of the subjects (cases or controls). Findings also showed accumulation of talc in the cytoplasm of tissue macrophages in several of the tissue sites of the five cases, which may substantiate the inflammatory potential of talc. Finally, this study supports the hypothesis of the migration of talc from the perineal region through lymphatic pathways by demonstrating the presence of talc in multiple pelvic tissues and lymph nodes simultaneously (McDonald et al. 2019a). Some further work was done (Johnson et al. 2020) to compare talc particles from commercially available powders to those found in pelvic tissues taken from 11 randomly selected ovarian cancer patients with a known history of long-term perineal talc use. PLM and SEM/EDX were employed to measure the talc particles, and extensive measures were taken to control for contamination. The talc particles taken

from tissues of the patients were most often located within benign tissue, reactive fibroblastic tissue, or chronically inflamed tissue near a tumour, rather than within tumours; the presumption is that talc accumulates in benign tissue some time prior to the tumour developing. The particle size and dimensions of talc particles found in the commercial samples are consistent with those found in the pelvic tissues of the patients: 77.7% of commercial samples and 83.5% of talc from tissues fall within the same ranges for aspect ratio and area. This lends support to the idea that externally-applied talc can migrate from the perineal area (Johnson et al. 2020).

The effect of talc particles in the presence of estrogen was investigated in culture with murine ovarian surface epithelial cells. Co-stimulation of macrophages with estradiol and talc produced an additive effect on reactive oxygen species production and permitted a higher number of cancer cells to survive. Talc alone, and especially in combination with estradiol, produced changes in gene expression that could have promoted a pro-tumorigenic environment and less efficient tumoricidal activity of the macrophages. Control particles (titanium dioxide, urban air particulates or diesel exhaust particles) did not produce the same effects (Mandarino et al. 2020). These results align with the earlier findings of Buz'Zard and Lau (2007) that talc increased cell proliferation and reactive oxygen species generation and induced neoplastic transformation in ovarian cells and polymorphonuclear neutrophils *in vitro*, suggesting that it may contribute to ovarian neoplastic transformation. Similarly, talc was noted to induce a greater inflammatory response than other poorly soluble particles in a recent study in hamsters (Sato et al. 2020). Collectively, these results suggest that talc is different from other poorly soluble particles and demonstrates a tumour-promoting activity.

Another possible mode of action put forth in the scientific literature is immune mediated. It has been suggested that talc particles need not reach the ovaries but only need to reach the lower genital tract, where they could trigger changes (such as the production of heat shock proteins and/or decreased levels of antibodies) that could contribute to ovarian cancer (Cramer et al. 2005; Muscat et al. 2005). Human mucin 1 (MUC1) is expressed in high levels by ovarian cancer (Gendler and Spicer 1995; Deng et al. 2013). Mucins are proteins involved in the formation of mucous barriers on epithelial surfaces (Gendler and Spicer 1995). Anti-MUC1 antibodies may have a protective effect; patients generate immunity against MUC1 produced by their tumours (Cramer et al. 2005). The Cramer et al. (2005) study used an enzyme-linked immunosorbent assay to measure anti-MUC1 antibodies in women. It was found that the use of talc in the perineal area was associated with significantly decreased levels of antibodies to MUC1. Cramer (2012) further hypothesized that chronic talc use can affect the tissues that express MUC1, leading to an immune-tolerance and lower anti-MUC1 antibodies, thus increasing the risk for ovarian cancer. Pinheiro et al. (2010) also studied anti-MUC1 levels and ovarian cancer in a large cohort. Although the results were not stratified with respect to talc use specifically, the authors found that anti-MUC1 antibodies, when evaluated several years prior to diagnosis, may be associated with decreased risk of ovarian cancer in subjects less than 64 years of age at assessment.

Animal studies

While some animal studies have investigated the effect of talc on the ovaries, rodents are poor experimental models for perineal studies for a number of reasons. Ovulation, including the number of oocytes generated and the length of cycle, is markedly different in rodents compared to humans (Chaffin and VandeVoort 2013). In general, epithelial ovarian tumours are rare in rodents, possibly due to the bursa surrounding the ovaries. The ovarian bursa is lacking in humans, but is necessary for normal ovulation and reproduction in rodents. This membranous pouch may offer some protection of the surface epithelium from local carcinogens (Nishida et al. 1998; Li et al. 2007). Ovarian tumours can occur in some strains of mice and rats; however, the low incidence and the length of time required for the appearance of tumours are limitations of experimental studies testing ovarian carcinogenesis (Vanderhyden et al. 2003). On account of the limitations detailed above, in addition to the challenges posed by exposing animals via the perineal route, animal data are very limited; one single-dose study (Hamilton et al. 1984) and one short-term repeated-dose study were available (Keskin et al. 2009).

A single injection of talc (in saline; 100 µl) into the bursa around the ovaries of 10 rats resulted in a cystic appearance due to distension of the bursal sac. Foreign-body granulomas without surrounding inflammation were documented in five ovaries and papillary changes were seen in the surface epithelium in four ovaries. The presence of talc was confirmed; however, the study authors hypothesized that the results could also be due to long-term exposure to steroidal hormones present in the entrapped follicular fluid within the distended bursa (Hamilton et al. 1984).

Daily perineal or intravaginal application of talc (100 mg in 0.5 ml in saline; aerosol form) to rats (n = 7) for 3 months produced evidence of foreign-body reaction, findings of infection and an increase in the number of inflammatory cells in all genital tissues (vulva, vagina, uterus, fallopian tubes, and ovaries). Two control rats also had infections. There were no cancer or pre-cancer effects observed; however, the authors noted that the study duration may have been too short to note these types of effects (Keskin et al. 2009).

No chronic or carcinogenicity animal studies by the perineal route of exposure were identified in the literature for talc.

Human studies

Several meta-analyses of available epidemiological data, including both case-control and cohort designs, have been published. These studies have consistently reported a positive association with ovarian cancer and perineal talc exposure, with odds ratios (OR)s ranging from 1.22 to 1.35 (Huncharek et al. 2003; Langseth et al. 2008; Terry et al. 2013; Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019). Generally, the various meta-analyses were conducted with the same available

epidemiological studies. However, different studies were included or excluded for various reasons. There were also variations in defining criteria for inclusion of participants in the study, resulting in differences in the ORs for the individual studies considered. Despite this, the meta-analyses produced similar overall ORs with statistical significance. Table 7-1 shows a comparison of the three most recently published meta-analyses, namely those of Berge et al. (2018), Penninkilampi and Eslick (2018) and Taher et al. (2019).

Collectively, across the three most recent meta-analyses, there were 30 case-control studies and four cohort design studies. A high percentage of the case-control studies, 89% for Berge et al. (2018), 92% for Penninkilampi and Eslick (2018) and 85% for Taher et al. (2019), had calculated ORs greater than 1 (indicating a positive association). Approximately half of these were statistically significant. Three of the four cohort studies also reported ORs greater than 1. However, none were found to be statistically significant (Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019). Some considerations pertaining to the cohort and case-control design studies from the meta-analyses are noted below.

Cohort studies

There are 4 cohort studies used in the meta-analyses and reported in Table 7-1. Gertig et al. (2000) and Gates et al. (2010) reported on the same cohort, i.e., the Nurses' Health Study (NHS). The NHS began in 1976 and targeted married registered nurses aged 30 to 55 years living in the 11 most populous states; 71% of those targeted returned the questionnaire. The questions pertaining to perineal powder use were not added until 1982 and were only asked once (i.e., at baseline in 1982). Participants were asked if they ever commonly used talcum, baby or deodorizing powder applied to the perineal area or sanitary napkins (NHS 2020). Gates et al. (2010) followed the subjects for 24 years (1982 to 2006), but did not assess never-users in a manner similar to other epidemiological studies. Rather, they combined the never-users with those that used powders "less than once a week." Gertig et al. (2000) accounted for the never-users alone, but their study had only 14 years of follow-up. Limitations recognized by the authors of both studies include lack of detailed exposure data (e.g., age at which use began, duration of use) and potential exposure misclassification, since the question pertaining to genital powder use was not specific to talc (Gertig et al. 2000; Gates et al. 2010). Gertig et al. (2000) also highlight the relatively short follow-up period. Gates et al. (2010) note that the greater degree of exposure misclassification over 24 years of follow up is a possible explanation for the difference in association reported in Gertig et al. (2000).

Houghton et al. (2014) used the cohort generated in the Women's Health Initiative (WHI). The original WHI study began in 1993 and concluded in 2005. Since 2005, the WHI has continued through extension studies. The subjects were limited to post-menopausal women between the ages of 50 to 79 from 40 clinical centres across the United States. As in the case of the NHS, the question pertaining to genital powder use

was not specific to talc (talc, baby, deodorizing powder) and was only asked at baseline (WHI 2020). Houghton et al. (2014) reported a mean follow-up period of 12.4 years. Duration of use was accounted for, but frequency of use was not. As noted by study authors, had both duration and frequency of use been accounted for, a better measure of intensity of use could have been conducted to assess dose-response. Other limitations mentioned by the study authors included a lack of information regarding oophorectomy after baseline and the potential for non-differential misclassification of exposure (participants still needed to recall past use and duration) (Houghton et al. 2014).

In the final cohort study, Gonzalez et al. (2016) used data collected in the Sister Study. The Sister Study was started in 2003 and recruited women aged 35 to 74 years residing in the United States and Puerto Rico who had a sister diagnosed with breast cancer. Questions regarding powder use asked at baseline were specific to talc powder, but focused only on use during the ages of 10 to 13 years as well as use in the past 12 months¹² (Sister Study 2020). Results of the Gonzalez et al. (2016) study produced the lowest calculated OR (0.73). However, the follow-up period was the shortest of all the cohort studies (less than 7 years) and talc use was assessed only for the 1-year period before the study; both of these factors were recognized as limitations by the authors. As well, as breast cancer is a risk factor for ovarian cancer development, this cohort may not be representative of the general population, since subjects are more likely than the general population to develop ovarian cancer (Gonzalez et al. 2016).

A recent analysis by O'Brien et al. (2020) revisited the available cohort studies. Data from four cohort studies (NHS, WHI, SIS and NHS II) were pooled for a total sample size of over 250 000 women. Additional cases (from the previous publications above) and a median of 11.2 years of follow-up were included. O'Brien et al. (2020) is the only published analysis that included data collected from the NHS II. The NHS II was established in 1989 and focused on oral contraceptive use, thus targeting a younger population (aged 25 to 42 years). Only a single mail-out was done, resulting in a 24% response rate. The questions regarding perineal powder use ("at least weekly") were not added until 2013 (NHS 2020), which means that fewer than 4 years of follow-up was available for the O'Brien et al. (2020) analysis. The overall OR reported by O'Brien et al. (2020) was 1.08 [0.99-1.17], and the authors concluded that there was not a statistically significant association between perineal powder use and ovarian cancer. However, the study authors recognized that the study may have been underpowered to detect a small increase in risk. Several limitations were also recognized with respect to the exposure assessment (e.g., no data collected on use after baseline, variation on exposure

¹² The Sister Study did ask again about talc powder use, including more specific questions with respect to exposure, in 2017-2019. However, data collected from these more recent questionnaires has not yet been analyzed/published.

categories, missing duration/frequency information) as well as overall limited generalizability (O'Brien et al. 2020).

Case-control studies

There are 30 case-control design studies used in the meta-analyses and reported in Table 7-1. When the studies are pooled, they generate a substantial sample size with data from different countries/geographical areas, representing a wide variety of ethnicities. As is evident in Table 7-1, the sample sizes range considerably across the studies. There are also differences in the prevalence of powder use as well as response rates, both across the studies and, typically to a lesser degree, between the cases and controls within the same study. For example, the response rates were very high for both cases (90%) and controls (94%) in Tzonou et al. (1993), whereas they were low (40% and 57%, respectively) for Mills et al. (2004). The response rate was sometimes better among cases (e.g., Merritt et al. 2008; Cramer et al. 2016) and sometimes, but less often, better among controls (e.g., Chen et al. 1992; Cook et al. 1997). Response rates were not available for all studies. Prevalence of talc use also varied, sometimes considerably, across and/or within (cases vs controls) studies. Several studies had prevalence rates for both cases and controls of over 40% (Whittemore et al. 1988; Harlow et al. 1992; Merritt et al. 2008; Schildkraut et al. 2016), whereas some reported prevalence rates of less than 10% (Chen et al. 1992; Tzonou et al. 1993), suggesting that prevalence of use may perhaps be dependent on ethnic background.

The selection of participants was restricted within each study to certain geographical areas, and some were further restricted to certain ethnicities and/or to language spoken. The specificity of the questions asked varied; some studies included questions about talc use as part of a larger questionnaire covering several potential risk factors, while other studies were more focused on talc use with detailed exposure questions (e.g., frequency, duration, brand used). The questions were almost always administered via an in-person or telephone interview by trained administrators (versus self-administered mailed questionnaires). Finally, the selection of controls differed across the studies; the majority used population-based control groups, while others chose to match cases to hospital-based controls.

A number of common limitations were recognized by the authors of the various case-control studies:

- small sample sizes (Rosenblatt et al. 1992; Tzonou et al. 1993; Ness et al. 2000; Langseth and Kjaerheim 2004; Mills et al. 2004; Moorman et al. 2009)
- limited exposure information collected (Booth et al. 1989; Harlow and Weiss 1989; Green et al. 1997; Wong et al. 1999; Rosenblatt et al. 2011)
- reliance on self-reporting (Chang and Risch 1997; Green et al. 1997; Schildkraut et al. 2016)
- low response rates, potential differences of powder use between cases and controls or not interviewing all eligible participants (Cramer et al. 1982; Whittemore et al. 1988; Chen et al. 1992; Harlow et al. 1992; Purdie et al. 1995;

Chang and Risch 1997; Cook et al. 1997; Ness et al. 2000; Mills et al. 2004; Merritt et al. 2008; Moorman et al. 2009; Rosenblatt et al. 2011; Wu et al. 2015) and

- potential for recall bias (Hartge et al. 1983; Purdie et al. 1995; Wong et al. 1999; Mills et al. 2004; Gates et al. 2008; Rosenblatt et al. 2011; Cramer et al. 2016).

Table 7-1. Available human epidemiological studies investigating the association between perineal use of talc and ovarian cancer (Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019)

Reference	OR [95% CI]	OR [95% CI]	OR [95% CI]
Total sample size (# cases)	(Berge et al. 2018)	(Penninkilampi and Eslick 2018)	(Taher et al. 2019)
Booth et al. 1989 ^a 686 (235)	1.29 [0.92-1.80]	1.30 [0.94-1.80]	Not included
Chang and Risch 1997 ^a 1014 (450)	1.35 [1.03-1.76]	1.42 [1.08-1.86]	1.42 [1.08-1.87]
Chen et al. 1992 ^a 336 (112)	3.90 [0.91-10.60]	3.90 [1.43-10.60]	Not included
Cook et al. 1997 ^a 735 (313)	1.50 [1.10-2.00]	1.50 [1.11-2.02]	1.60 [1.10-2.33]
Cramer et al. 1982 ^a 430 (215)	1.92 [1.27-2.89]	1.60 [1.21-2.12]	1.92 [1.27-2.90]
Cramer et al. 2016 ^a 4141 (2041)	1.32 [1.14-1.50]	1.42 [1.03-1.95]	1.32 [1.15-1.51]
Gates et al. 2008 ^a 3187 (1385)	Not included	Not included	1.36 [1.14-1.62]
Godard et al. 1998 ^a 305 (153)	2.49 [0.94-6.58]	2.49 [0.94-6.58]	2.49 [0.94-6.60]
Goodman et al. 2008 ^a 602 (387)	0.99 [0.70-1.41]	Not included	Not included
Green et al. 1997 ^a 1684 (824)	Not included	1.30 [1.06-1.60]	1.30 [1.10-1.54]
Harlow and Weiss 1989 ^a 274 (116)	1.10 [0.70-2.10]	1.10 [0.58-2.10]	1.10 [0.70-1.73]
Harlow et al. 1992 ^a 474 (235)	1.50 [1.00-2.10]	Not included	1.50 [1.00-2.25]
Hartge et al. 1983 ^a 306 (135)	2.50 [0.70-10.00]	2.50 [0.66-9.45]	0.70 [0.40-1.22]
Kurta et al. 2012 ^a 2704 (902)	Not included	1.40 [1.16-1.69]	1.40 [1.16-1.69]
Langseth and Kjaerheim 2004 ^a 225 (46)	Not included	Not included	1.15 [0.41-3.23]

Reference	OR [95% CI]	OR [95% CI]	OR [95% CI]
Total sample size (# cases)	(Berge et al. 2018)	(Penninkilampi and Eslick 2018)	(Taher et al. 2019)
Lo-Ciganic et al. 2012^a 2704 (902)	1.34 [1.07-1.66]	Not included	Not included
Merritt et al. 2008^a 3085 (1576)	1.13 [0.92-1.38]	1.17 [1.01, 1.36]	1.17 [1.01, 1.36]
Mills et al. 2004^a 1354 (249)	1.37 [1.02-1.85]	1.37 [1.02-1.85]	1.37 [1.02-1.84]
Moorman et al. 2009^a 2143 (1086)	1.37 [1.05-1.80]	Not included	1.06 [0.85-1.32]
Ness et al. 2000^a 2134 (767)	1.50 [1.10-2.00]	1.50 [1.10-2.02]	1.50 [1.10-2.05]
Purdie et al. 1995^a 1684 (824)	1.27 [1.04-1.54]	1.27 [1.04-1.54]	Not included
Rosenblatt et al. 1992^a 123 (77)	1.70 [0.70-3.90]	1.70 [0.72-4.01]	1.00 [0.20-5.00]
Rosenblatt et al. 2011^a 2125 (812)	1.13 [0.93-1.36]	1.27 [0.97-1.66]	1.27 [0.97-1.66]
Schildkraut et al. 2016^a 1329 (584)	1.44 [1.11-1.86]	1.44 [1.11-1.86]	1.44 [1.11-1.87]
Shushan et al. 1996^a 686 (235)	Not included	2.00 [1.11-3.60]	Not included
Tzonou et al. 1993^a 389 (189)	1.05 [0.28-3.98]	1.05 [0.28-3.96]	1.05 [0.28-3.94]
Whittemore et al. 1988^a 727 (188)	1.36 [0.91-2.04]	1.40 [0.98-2.00]	1.45 [0.81-2.60]
Wong et al. 1999^a 1155 (462)	1.00 [0.80-1.30]	0.92 [0.24-3.57]	1.00 [0.80-1.25]
Wu et al. 2009^a 1297 (609)	Not included	Not included	1.53 [1.13-2.07]
Wu et al. 2015^a 4092 (1701)	1.46 [1.27-1.69]	1.32 [1.14-1.52]	1.46 [1.27-1.68]
Gates et al. 2010^b 108870 (797)	1.06 [0.89-1.28]	Not included	Not included
Gertig et al. 2000^b 78630 (307)	Not included	1.09 [0.86-1.38]	1.09 [0.86-1.38]
Gonzalez et al. 2016^b 41654 (154)	0.73 [0.44-1.20]	0.73 [0.44-1.20]	0.73 [0.44-1.21]

Reference	OR [95% CI]	OR [95% CI]	OR [95% CI]
Total sample size (# cases)	(Berge et al. 2018)	(Penninkilampi and Eslick 2018)	(Taher et al. 2019)
Houghton et al. 2014 ^b 61285 (429)	1.06 [0.87-1.28]	1.12 [0.92-1.36]	1.12 [0.92-1.36]
Overall OR	1.22 [1.13-1.30]	1.31 [1.24-1.39]	1.28 [1.20-1.37]

Abbreviation: CI, confidence interval.

^a Case-control study

^b Cohort study

Evaluation of causation

The Hill considerations are a set of factors (i.e., strength, consistency, specificity, temporality, biological gradient, biological plausibility, coherence, experiment and analogy) that can form a framework for evaluating evidence in humans to help determine whether observed associations may be causal (Hill 1965; Coglianò et al. 2004; U.S. EPA 2005; Fedak et al. 2015).

Established several decades ago, the Hill considerations continue to be employed today, with some modified interpretations; there is general consensus that some factors hold more weight than others. Strength, consistency and biologic gradient are most frequently considered. Conversely, experiment, analogy and specificity are often considered to be less significant, or to hold less weight, in the decision-making framework (Grimes and Schultz 2002; Carson 2018; Kane 2018; Moorman 2018; Singh 2018; Smith 2018; Wolf 2018; Ballman 2019; Diette 2019; Merlo 2019). Temporality, namely that exposure precedes the disease, is another factor that is rarely elaborated upon as it is crucial for the determination of a causal relationship and therefore seldom warrants further discussion. In addition to these factors, other elements such as bias, chance, error and confounding are also important. The likelihood of a causal association is strongest when these elements can be minimized (Hill 1965; Weed and Gorelic 1996; Coglianò et al. 2004; Franco et al. 2004; U.S. EPA 2005; Fedak et al. 2015).

In relation to perineal talc exposure and ovarian cancer, strength, consistency, biological gradient and biological plausibility are discussed below.

Strength

Strength of association is typically a consideration of the relative risk (or OR) between the chemical exposure and the disease. A large risk increases confidence of a causal relationship; however, risks of lower magnitude do not preclude a positive association and rather, may represent a low level of exposure or a rare disease (Hill 1965; Coglianò et al. 2004). The pooled ORs from available meta-analyses ranged from 1.22 to 1.35 (Huncharek et al. 2003; Langseth et al. 2008; Terry et al. 2013; Berge et al. 2018;

Penninkilampi and Eslick 2018; Taher et al. 2019), which would not be considered “large.” However, the results for the pooled analyses are statistically significant, with narrow confidence intervals. As noted in Table 7-1, a high proportion of available case-control studies representing a broad section of the population have reported strikingly similar ORs. Ovarian cancer is recognized as a rare disease (AICR 2020; CTFPHC 2020; NCI-SEER 2020) and, as such, the large number of studies giving similar results is noteworthy.

Some authors argue that the small strength of association (OR approximately 1.3) can be explained by bias and/or confounding (see *Bias and confounding* section below) and is therefore not an indication of causation (Diette 2019; Merlo 2019; Moore 2019). Others, while not disputing that the association is modest, argue that the factor has been satisfied as an indication of causation (Kane 2018; Moorman 2018; Siemiatycki 2018; Singh 2018; McTiernan 2019). Moorman (2018) and Smith-Bindman (2018) contend that perineal talc use is common among women in the epidemiological studies and therefore even a modest increase in risk is of concern to the population. Ballman (2019) raises the argument that such statements assume that the association is causative.

Strength and consistency of association are two factors often considered together. The replication of results seen across multiple studies supports strength (Singh 2018). The measured ORs (1.22 to 1.31) are modest, but they are also similar and unlikely to be random. Considering that ovarian cancer is rare, and therefore that a large data set is required to detect an association, the findings in the available literature are significant.

Consistency

As described by Hill (1965), consistency considers whether the observed association has been replicated by different people, in different places, under different circumstances and at different times. The epidemiological studies examined in the meta-analyses were conducted over different time periods (across more than four decades), among different ethnicities, and spanned many cities/communities/countries worldwide (Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019). The pooled ORs calculated in the three most recent meta-analyses, 1.22 (Berge et al. 2018), 1.31 (Penninkilampi and Eslick 2018) and 1.28 (Taher et al. 2019), which suggest a 22% to 31% increase in risk, are consistent with those calculated in older studies, i.e., 1.33 (Huncharek et al. 2003), 1.35 (Langseth et al. 2008) and 1.24 (Terry et al. 2013). As highlighted in Table 7-1, a high percentage (91%) of the epidemiology studies examined had ORs greater than the null (1.0) and overall consistent values despite being conducted by different authors using varied methodologies. The general direction and strength of the association is consistent (Singh 2018). Several of the individual values lack statistical significance; however, given the rarity of ovarian cancer, many of the available human studies may not be sufficiently powered to detect a low OR; sample sizes were often not large enough to detect a 20% to 30% increase in risk, even when pooled (Narod 2016; McTiernan 2019, O'Brien et al. 2020).

Measures of consistency,¹³ i.e., quantification of heterogeneity, have been reported in two of the recent meta-analyses and support the view that the results across the epidemiological studies are consistent (Penninkilampi and Eslick 2018; Taher et al. 2019). However, the disproportionate number of case-control studies versus cohort studies may affect this significance (Ballman 2019).

Greater consistency across the different study types (cohort vs case-control designs) would increase the likelihood of a causal relationship. The major disadvantage of case-control studies is that they can be prone to recall bias. Cohort studies minimize selection and recall biases, but they require long follow-up times and a large number of participants, in particular for rare outcomes, in order to achieve requisite power. Since cohort studies require these additional resources, they also tend to target multiple research questions to gather information on several exposures and outcomes (Celentano and Szklo 2019). Specific to talc and ovarian cancer, some recent analyses have given precedence to the results of the cohort studies, arguing that they provide stronger evidence for an association than case-controls (Ballman 2019; Moore 2019; Goodman et al. 2020; Johnson & Johnson Consumer, Inc. 2020). Other analyses support the view that such generalizations cannot be made and that there are many factors affecting the validity of a study regardless of design (Moorman 2018; Siemiatycki 2018; Smith-Bindman 2018; McTiernan 2019).

The available cohort studies did not demonstrate the same level of statistical significance as was seen in the case-control studies. Perspectives vary among authors with respect to statistical significance: some (Diette 2019; Merlo 2019; Moore 2019) regard it as critical, whereas others (Narod 2016; Siemiatycki 2018; McTiernan 2019) argue that it is not. A recent paper by Amrhein et al. (2019) argues that “a statistically non-significant result does not ‘prove’ the null hypothesis.” A confidence interval that contains the null value often also contains non-null values of importance and should not be used to conclude that there is no association; values just outside the interval are not substantially different from those within the interval. Ovarian cancer is expected to have a long latency period, with estimates of 15 to 40 years (Purdie et al. 2003; Gonzalez et al. 2016; Tran et al. 2019). It is not known whether the follow-up periods in the cohort studies were adequate to detect a potential association between perineal talc exposure and ovarian cancer. As cited above, the cohorts, even when pooled together, may not be sufficiently powered. Cohort studies are less desirable than case-control studies for

¹³ I^2 represents the percentage of variation across studies that is due to heterogeneity rather than chance; an I^2 of 0% represents no heterogeneity and larger I^2 values indicate increasing heterogeneity (Higgins et al. 2003). Penninkilampi and Eslick (2018) used Cochran’s Q statistic to derive an I^2 statistic of 10.52% for any perineal use, where $I^2 = 25\%$ is considered low heterogeneity and 50% would be considered moderate. Taher et al. (2019) also conducted a heterogeneity test and reported an $I^2 = 33\%$ for ever vs never talc use.

rare diseases because case-control studies can generate a much larger number of cases. Referring to Table 7-1, the number of cases (797) in the largest cohort study (Gates et al. 2010) is considerably lower than the number of cases (2041) in the largest case-control study (Cramer et al. 2016), whereas the sample sizes are considerably larger in the cohort study, namely 108 870 compared to 4141 in the case-control study (Bindman 2018; Penninkilampi and Eslick 2018; Singh 2018; Celentano and Szklo 2019;). Related to adequacy of follow-up time is the age of participants in the cohort studies. The median age of ovarian cancer diagnosis is 63 (NCI-SEER 2020). In the O'Brien et al. (2020) analysis, two of the cohorts (NHS II and SIS) representing nearly 40% of the sample size are made up of younger populations, with many of the individuals at or below the median age of diagnosis, indicating that cancer incidences may not yet be detectable. At least some of the cohorts may still be too recent and limited to illustrate the true outcome of a rare disease.

None of the cohort studies accounted for both sufficient follow-up time and comparable exposure groups. Diette (2019) and Merlo (2019) note the idea that the cohort studies could sufficiently account for the latency of ovarian cancer since powder use likely started long before the beginning of the study. Other limitations of the cohort studies include the following:

- The questions regarding powder use were only administered once, and in several cases not until several years following the initiation of the study, which could bias the findings towards null (Moorman 2018; Singh 2018, McTiernan 2019; O'Brien et al. 2020). Ballman (2019) also recognizes this as a limitation but considers it to be minimal since the duration of powder use among ever-users can be extensive (> 20 years).
- The cohort studies all limited their subjects considerably (e.g., post-menopausal, a sister with breast cancer, registered nurses) and may not represent the general population. O'Brien et al. (2020) recognizes that collectively, these cohorts are predominately white, highly educated and not obese, which could limit generalizability.
- The question related to powder use was often not specific to talc and could have included other powders, which could bias the findings towards null (Singh 2018; Tran et al. 2019). Smith-Bindman (2018) and McTiernan (2019) suggest that differences in exposure measurement and specificity of study design may explain the apparent discrepancy in results between the case-control and the cohort studies. For example, cohort studies only measured exposure at study entry and were designed to look at several exposures and diseases, while most case-control studies were designed to specifically address perineal talc use and ovarian cancer risk.

Over 90% of the studies examined (case-control and cohort) calculated a positive association between talc use and ovarian cancer. Consistent values were recorded, with overall ORs from the recent meta-analyses ranging from 1.22 to 1.31. It is recognized that there is some inconsistency between results from case-control studies versus cohort studies, in particular with respect to the degree of statistical significance.

However, this could be explained by the limitations of the cohort studies described above. Overall, there is a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the world.

Biological gradient

Being able to support a biological gradient or dose-response relationship is another important factor in establishing causation. Some authors suggest that the available data show no clear or consistent trend with respect to dose (e.g., frequency, duration of use) and response (Ballman 2019; Diette 2019; Johnson & Johnson Consumer, Inc. 2020). However, several studies (Harlow et al. 1992; Terry et al. 2013; Cramer et al. 2016; Schildkraut et al. 2016; Gabriel et al. 2019) do suggest a trend of increased OR with increased cumulative exposure. Meta-analyses conducted by Berge et al. (2018) and Penninkilampi and Eslick (2018) report a weak trend with duration and frequency of genital talc use and a slight association with respect to length of talc use, respectively. Taher et al. (2019) isolated seven studies that provided some evidence of increased risk of ovarian cancer with increasing perineal applications of talc; however, none demonstrated both a clear dose-response trend and statistical significance. Several of these studies are cited by the authors as evidence in support of biological gradient, but the limitations of the available data prevented this factor from contributing heavily to the decision making framework (Moorman 2018; Siemiatycki 2018; Singh 2018; Smith-Bindman 2018; Wolf 2018; McTiernan 2019). McTiernan (2019) notes that a typical dose-response relationship may not be necessary since ovarian talc particle burden may not be associated with the number of applications; it may be a substance where there is no safe dose. Similarly, Terry et al. (2013) noted that the association may not be linear. Many of the studies only assessed a single dose level (ever-users vs never-users). Furthermore, data with respect to the types of powder used by subjects or the amounts applied were not presented, and therefore a relationship between the concentration/dose of talc in the powder and the incidence of ovarian cancer could not be investigated.

Collectively, there is significant exposure information lacking to permit a fulsome assessment of biological gradient.

Biological plausibility

According to Hill (1965), biological plausibility is helpful to determine causality but is “a feature that cannot be demanded.” Particles of talc are able to migrate into the pelvis and ovarian tissue, possibly causing irritation and inflammation. Although a specific order of events by which perineal talc exposure could lead to ovarian cancer has not been established, several recent publications (Campion et al. 2018; Fletcher et al. 2019; McDonald et al. 2019a; McDonald et al. 2019b; Mandarino et al. 2020) support the hypothesis that perineal talc exposure leading to ovarian cancer is biologically plausible. Several authors (Kane 2018; Moorman 2018; Siemiatycki 2018; Singh 2018; Smith 2018; McTiernan 2019) agree that the factor of biological plausibility has been met,

even in the absence of many of the recent studies which would not have been available at the time of their analyses. Building from ideas introduced by Hill (1965), these authors suggest that biological plausibility depends on current state of scientific knowledge and should not rest on demonstrated proven mechanisms to consider this factor “satisfied”, but rather whether the hypotheses “make sense” or are scientifically possible. Siemiatycki (2018) provides several examples from the history of medicine and epidemiology where associations were demonstrated as causal long before the mechanisms were validated. Others authors, however, argue that the factor has not been met or has only weakly been satisfied or that theories are not substantiated (Ballman 2019; Diette 2019; Moore 2019; Neel 2019). Ballman (2019) suggests that since the ability to predict plausibility has advanced, the expectations of “sounding reasonable”, set decades ago, need to be exceeded. These authors reason that there is lack of support in the scientific literature to demonstrate the relationship between perineal users vs non-users and the particle load found in tissues.

The recent study by McDonald et al. (2019b), which likely was not available at the time of the authors’ analyses, does demonstrate increased talc burdens in genital talc users compared to non-users and indicates that there is a high likelihood of sample contamination without extreme measures to control it, suggesting that talc burden in non-users reported in older studies was possibly a result of sample contamination. The assessment by Goodman et al. (2020) did consider recent publications on the mechanistic evidence and concluded that there is insufficient support for any proposed mechanism.

Overall, the available animal and human studies described under *Mode of action* above clearly indicate that particles, including talc, may transfer from the vagina to the fallopian tubes and ovaries following perineal application. Recent research with respect to specific mechanisms (inflammation and/or tumour precursor events) add increased support to the biological plausibility.

Bias and confounding - other elements for consideration

In order to increase the confidence of causal inference, bias, chance, error and confounding need to be ruled out or minimized. There are a range of opinions as to the extent to which these factors may influence the available epidemiological data. Chance is unlikely to play a significant role since the distribution of ORs across the epidemiological studies is not random (McTiernan 2019; Siemiatycki 2018).

There are many unknowns with respect to the causes of ovarian cancer, making it difficult to account for all confounders. Age, race, low parity, infertility, and a family history of certain cancers are among the most likely risk factors in the etiology of epithelial ovarian cancer (Fiume et al. 2015), with age and parity considered key (Taher et al. 2019). Most of the human epidemiology studies reported effects adjusted for a variety of these potential confounders. It is possible that one or more confounders exist and may be at play in the epidemiological studies for perineal talc use that have not yet

been recognized as such (Diette 2019; Merlo 2019). Overall, although confounding cannot be definitively excluded, significant efforts have been made to adjust for the recognized confounders.

The possibility of biases and/or errors are recognized throughout the literature. There are potential sources of biases/errors and the impact can differ depending on the study design. In general, case-control studies are more susceptible to biases. Some authors think that these other factors (i.e., bias, confounding, error) are sufficient in the case-control studies to account for the apparent positive association (Ballman 2019; Diette 2019; Merlo 2019; Moore 2019; Goodman et al. 2020; Johnson & Johnson Consumer, Inc. 2020), whereas others, although not disputing the existence of these other factors, conclude that they are unlikely to account completely for the consistent associations produced across the studies (Rosenblatt et al. 2011; Schildkraut et al. 2016; Moorman 2018; Siemiatycki 2018; Singh 2018; McTiernan 2019).

Recall bias, unique to case-control studies, is of note with respect to perineal talc use and ovarian cancer. Recall bias occurs when individuals in a study tend to have a more vested interest and over-report the retrospective exposure, leading to potential over-estimation of risk. Conversely, the controls may under-report. Some authors (Cramer 2016; Narod 2016; Berge et al. 2018; Penninkilampi and Eslick 2018; Siemiatycki 2018) argue that recall bias does not factor strongly in the case of perineal talc exposure and risk of ovarian cancer. In studies where the exposure is simple (e.g., never- vs ever-use), recall bias is unlikely to be an important source of bias (Narod 2016). According to Penninkilampi and Eslick (2018), the potential for recall bias can be decreased when the exposure of interest (i.e., talc use) is part of a more extensive questionnaire, as is the case for many of the studies. Cramer et al. (2016) conducted a sensitivity analysis and determined there was an approximate 18% buffer to account for recall bias before the results of the study would be nullified; however, it could not be substantiated whether this is a reasonable buffer.

Recall bias can also be influenced by increased media attention (Muscat and Huncharek 2008; Penninkilampi and Eslick 2018). One recent case-control study in particular (Schildkraut et al. 2016) supports this, in which the calculated ORs for subjects interviewed after 2014, when lawsuits around talc and ovarian cancer were in the media, were considerably higher compared to those for subjects interviewed prior to 2014. However, looking at Table 7-1, the majority of the case-control studies used in the meta-analyses were conducted prior to this media attention, and the calculated ORs from the more recent studies are lower than many of those conducted much earlier. Two of the recent meta-analyses (Berge et al. 2018; Penninkilampi and Eslick 2018) used funnel plots as a mechanism to assess publication bias and reported an absence of concern.

Ovarian cancer – weight of evidence

There are no adequate animal models available to assess ovarian cancer risk due to perineal talc exposures. The animal models available do, however, note an inflammatory response in the reproductive tract of rodents exposed to talc particles. As well, recent research with respect to specific mechanisms add increased support to the biological plausibility, consistent with the possible human mode of action data for cancer development. The human database provides differing results between case-control and cohort studies. There is, however, support for the idea that despite greater susceptibility to biases, case-control designs are well suited to study perineal talc exposure and ovarian cancer. Furthermore, the available cohort studies are not without limitations. Overall, there is a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the world. Although there are uncertainties related to bias, there is confidence in the robustness of the available database for use in characterizing ovarian cancer risk attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship.

7.2 Exposure assessment

This exposure assessment focuses on routes of exposure where critical effects have been identified, namely non-cancer lung effects following inhalation of insoluble respirable particles of talc, and an association with ovarian cancer following perineal exposure to talc.

7.2.1 Environmental media, food and drinking water

Talc is a naturally occurring mineral, and there are several deposits in Canada (Kogel et al. 2006). Currently, there is one operating open-pit mine and concentrator, along with an operating mill (MAC 2019). However, no talc concentration data in ambient air or around open-pit talc mines and processing facilities have been reported. Although particulate matter data for inhalable and respirable particles are available in the vicinity of these facilities (NPRI 2018), they were not used in the exposure assessment as particulate matter released from facilities is expected to contain a mixture of substances and therefore the concentration would not reflect talc exposure from this source. Given the limited number of industrial and commercial sites producing and processing talc in Canada, talc exposure from ambient air is not expected to be significant.

Talc is insoluble in water (Table 3-1) and is expected to settle out during water treatment. Exposure to the general population from drinking water is not expected.

There is potential for oral (i.e., dietary) exposure resulting from the use of talc as a food additive, but exposure from these uses is expected to be minimal (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated February 27, 2018; unreferenced). Dietary exposure from the use of talc as a component in the manufacture of some food packaging materials is expected to be negligible and dietary

exposure is not expected from its use as a component in the manufacture of incidental additives (personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated February 27, 2018; unreferenced). Exposure from the oral route was not quantified because no critical health effects from the oral route of exposure have been identified. The JECFA has assigned an ADI of “not specified” for talc on the basis of low toxicity, and talc is considered “generally recognized as safe” for specific uses in food packaging in the United States (JECFA 2006; U.S. FDA 2019a, b).

7.2.2 Products available to consumers

As of 2020, talc is present as a medicinal or non-medicinal ingredient in approximately 10 000 self-care products in Canada, including approximately 150 non-prescription drugs, approximately 2100 NHPs, and approximately 7750 cosmetic products. In addition, there are approximately 1400 prescription drugs containing talc. There is therefore potential for oral exposure to talc resulting from the use of such products. However, exposure from the oral route was not quantified as no critical health effects from the oral route of exposure have been identified.

There is the potential for dermal contact with talc from the use of self-care products. Systemic exposure resulting from dermal contact with talc is expected to be negligible, as it is not expected that talc will be absorbed on the basis of its physical-chemical characteristics as an insoluble solid particle. In addition, a dermal health effect endpoint has not been identified for talc.

Notifications submitted under the *Cosmetic Regulations* to Health Canada for talc, the LNHPD (modified 2018), the Drug Product Database (DPD) (modified 2018), voluntary information submitted to Environment and Climate Change Canada and Health Canada (ECCC, HC 2017), publicly available databases and websites (e.g., Household Products Database 1993- ; CPCat 2014; CPID 2017), and material safety and technical datasheets were used to identify products where there is: (a) the potential for inhalation of insoluble respirable talc, and (b) the potential for exposure to the perineal region. These products and associated exposures are presented below.

No inhalation or perineal exposures for the general population were identified with respect to the major commercial or industrial uses of talc in paper, plastics, ceramics, and putties.

Inhalation exposure

Potential inhalation exposures were focused on products that were formulated as loose powders and were available to consumers, which included approximately 400 self-care products (primarily cosmetics). Available information of interest were self-care products marketed as cosmetics, natural health products, or non-prescription drugs that are intended for application to the body, face, eyes, lips, nails, feet, buttocks (babies), and

hair. The primary uses are as makeup, moisturizers and cleansers and to a lesser extent as antiperspirant/deodorants, hair removal products, dry hair shampoo, hair colour and nail polish. Concentrations of talc range from less than 10% to 100% in these types of products. Products formulated as pressed powders, which comprise the majority of cosmetics containing talc (approximately 5300 products), were not identified as a potential source of inhalation exposure of concern because these formulations contain coarser particles and binders, such as oils or waxes, which help bind the particles together and do not lead to the formation of a “dust cloud” available for inhalation.

Airborne inhalable and respirable-sized talc particles ($\leq 10 \mu\text{m}$ and $4 \mu\text{m}$, respectively) have been measured during the use of baby and body powders in several studies (Aylott et al. 1979; Russell et al. 1979; Anderson et al. 2017; Rasmussen et al. 2019). In order to confirm the size of talc particles in loose powder self-care products, Health Canada measured the particle-size distribution of four products (one baby powder, two adult body powder products, and one loose face powder) containing high concentrations of talc ($> 90\%$) available in Canada (Rasmussen et al. 2019). Using the Aerodynamic Particle Sizer (APS; TSI Inc. Model 3321), the particle-size distribution for the four products was determined to range from < 1 to $8 \mu\text{m}$, with median particle sizes ranging from 1.7 to $2 \mu\text{m}$ (Rasmussen et al. 2019). Thus, all of the particles were within the thoracic size fraction of inhalable particles ($\leq 10 \mu\text{m}$), and the median particle size was within the respirable range ($\leq 4 \mu\text{m}$), i.e., small enough to penetrate deep into the respiratory tract. Number concentrations measured using a scanning mobility particle sizer (SMPS; TSI Inc. Model 3788/3082) indicated that the proportion of nano-sized particles ($< 100 \text{ nm}$) was small ($< 10\%$) to negligible, depending on the product.

Several studies were conducted in the 1970s to provide data required to assess the safety of talc powder products and measure air concentrations (Pooley 1972; Aylott et al. 1979; Russell et al. 1979). These studies demonstrated that during the use of face, baby, and adult powders, there are quantifiable concentrations of respirable talc particles available for inhalation exposure. In 1972, Pooley measured respirable talc concentrations using gravimetric dust samplers in the breathing zone of infants and adults during diapering activities. Average respirable concentrations were the same for infants and adults at 8 mg/m^3 . The median size of respirable particles was approximately $1.74 \mu\text{m}$. In a 1979 study, Aylott et al. determined mean respirable air concentrations of 0.48 to 1.9 mg/m^3 of talc ($< 7 \mu\text{m}$) over 5 minutes for loose face powder, adult dusting powder, baby dusting powder, and micronized adult dusting powder (Aylott et al. 1979). That same year, concentrations of talc ($\leq 10 \mu\text{m}$) of 0.19 and 2.03 mg/m^3 , respectively, were determined near the infant breathing zone during a simulation of routine application of talcum powder during diapering and in the breathing zone of adults during the application of talcum powder to their body (Russell et al. 1979). In both Aylott et al. (1979) and Russell et al. (1979), the highest air concentrations were associated with the adult application of talcum powder to their bodies over infant diapering and application of loose facial powder. There are uncertainties with the calculated talc concentrations determined from these studies due

to limitations in the collection and analysis of talc concentrations resulting from the use of older personal air sampling and cyclone collecting equipment and methods used to quantify the concentration of talc in air (i.e., extrapolating from Mg measured using atomic absorption spectrometry (AAS), weight measurement on an early prototype quartz crystal mass monitor, conversion of gravimetric data to number concentrations).

In 2017, a study assessing the health risk from the use of cosmetic talc from historical products was published (Anderson et al. 2017). It examined talc products believed to have been manufactured and sold during the 1960s and 1970s to characterize airborne respirable dust concentrations during the use of these products. To quantify respirable talc concentrations in the breathing zone, five volunteers were asked to apply talc products as they typically would in a bathroom setting. Cyclone air sampling devices capturing PM₄ were attached to the breathing zone of each volunteer. Each exposure simulation consisted of eight application events, at 6-minute intervals, for a total sampling duration of 48 minutes. This study design ensured that the sample mass on the sampling filter was large enough for quantification and accuracy, but it was not expected that individuals apply talc every 6 minutes over a 48-minute window during the typical use of a talc body powder. Average talc concentrations over the 48-minute exposure simulation were calculated using the total measured mass (from eight applications over 48 minutes) and the air volume over the entire 48-minute sampling period. Respirable talc concentrations ranged from 0.26 to 5.03 mg/m³, and the average was 1.46 mg/m³. The average air concentration by subject ranged from 0.44 to 3.28 mg/m³. Respirable talc concentrations were more variable among all subjects and between subjects than per individual subjects, suggesting that individual behaviour and use patterns have a strong influence on airborne concentrations.

In 2018, Health Canada conducted a small study to measure air concentrations of particles in the breathing zone of adult volunteer subjects while they were applying talc-containing self-care products (Rasmussen et al. 2019). Continuous, direct-reading, personal breathing-zone monitors (positioned beside the nose) measured average concentrations of particulate matter of aerodynamic diameter of 4 µm or less (PM₄) on the subject of 0.48 ± 0.18 and 1.80 ± 0.82 mg/m³ for volunteers applying body powder (subject A) and loose face powder (subject B), respectively. Subjects repeated the application in triplicate. These average concentrations fall within the range of concentrations measured by Anderson et al. (2017). The application of loose face powder resulted in the highest average air concentration in the immediate vicinity of the nose. A third subject in the study applied talc to a wetsuit prior to donning (subject C); however, this activity was considered to be different than the use of talc as a self-care product. Mean airborne concentrations on subject C of 0.61 ± 0.09 mg/m³ were similar to those on subject A and B. However, the duration of the combined primary and secondary particle cloud was much longer at 700 ± 265 sec (subject C) versus 57 ± 8 sec (subject A) and 65 ± 7 sec (subject B). In this study, the cloud characteristics, concentration and duration varied. The variation may have resulted from the different purposes and methods of applying the talc product and from behavioural and physical differences among the subjects (Rasmussen et al. 2019).

Several exposure scenarios were identified where there was potential for inhalation exposure to talc particles from the use of self-care products, namely the use of baby, body, face, and foot powders (loose formulations) and dry hair shampoo. Although there may be differences in air concentrations of talc associated with the use of different types of self-care products (e.g., baby powder, foot powder), there is insufficient data available to generate reliable air concentrations for each use which would capture variability within and between subjects. Therefore, average air concentrations by subject from Anderson et al. (2017) were combined with the body and face powder replicates from Rasmussen et al. (2019) to obtain an overall average air concentration of 1.36 ± 0.97 mg/m³ available for inhalation exposure during the use of self-care products (Appendix A, Table A-1). Anderson et al. (2017) and Rasmussen et al. (2019) were considered to provide the best and most relevant available data as they not only utilized current collection instruments for air sampling and modern methods for quantifying talc but also presented data by subject, which was important as the variability among and between subjects is higher than within individual subjects and the combined sample size is relatively low to capture variability across the population (n = 7). The average air concentration value of 1.36 mg/m³ was used to estimate adjusted air concentrations for self-care products based on the highest concentration of talc present in these products. The results are summarized in Table 7-2. The inputs for each of these scenarios are outlined in Appendix A (Table A-2). Exposure to talc during application of loose powders on the eyes, lips and nails is expected to be lower than the estimates presented in Table 7-2 due to the smaller quantity of product applied and smaller area of application. Exposure to talc during the use of loose powder hair colour is expected to be similar to or lower than use of talc as a dry hair shampoo.

Table 7-2. Inhalation exposure estimates to talc from self-care products available to consumers

Product type	Age group	Average concentration in air per event (mg/m³)^a	Higher tier adjusted exposure concentration (mg/m³)^b
Baby powder 100% talc	Infant and adult	1.36	0.0071
Body powder 100% talc	Adult	1.36	0.0047
Face powder 100% talc	Adult	1.36	0.0047
Foot powder 97% talc	Adult	1.32	0.0034
Dry hair shampoo 100% talc	Adult	1.36	0.0011

^a Average measured air concentrations (Anderson et al. 2017, Rasmussen et al. 2019) × the highest concentration of talc in product type.

^b Refer to Appendix A, Table A-2 for details.

Perineal exposure

Several types of self-care products containing up to 100% talc are used in the perineal region of the body to reduce moisture and odour. Adult body powders used in the perineal region for feminine hygiene practices are still available on the Canadian market, although there has been a decline in this use over time (Houghton et al. 2014; Narod 2016). Baby powder products containing up to 100% talc are used in the perineal region of infants during diapering. In addition, there are a small number of diaper or rash cream self-care products (fewer than 10) for use in the perineal region which contain low concentrations of talc as a non-medicinal ingredient. Talc is permitted as a medicinal ingredient in diaper rash products at concentrations from 45% to 100% (Health Canada 2018). However, there are no diaper rash products listed in the LNHPD (modified 2018) containing talc as a medicinal ingredient.

Additional self-care products that have the potential for perineal exposure include antiperspirants and deodorants (e.g., genital antiperspirants), body wipes, bath bombs and bubble bath, and to a lesser extent (due to wash off or removal) other bath and shower products (i.e., soap, wash/gel, scrub) and products associated with hair removal (e.g., epilatory products). These products are formulated as gels, sprays, loose powders, and solid cakes and range in concentration from less than 1% to 100% talc.

As indicated in Section 4, there is no evidence to suggest that talc is currently being used as a dry lubricant on condoms or medical examination gloves in Canada. At present, these are not considered to be sources of perineal exposure.

While there are known sources of perineal exposure to talc, the available literature does not permit a quantitative assessment of perineal exposure from the use of self-care products.

7.3 Characterization of risk to human health

Consistent with other international regulatory and advisory bodies (Danish EPA, U.S. EPA, MAK-Commission, U.S. FDA, and JECFA), no critical health effects were identified for talc via the oral or dermal routes of exposure. As such, oral exposures to talc resulting from food intake and oral and dermal exposure from the use of self-care products are not of concern.

Considering available lines of evidence, critical health effects have been identified following inhalation exposure to respirable talc particles. The available health effects data are adequate and study outcomes are consistent in providing a high degree of confidence in the assessment of health outcomes following inhalation exposure to talc particles. From the available toxicological studies, a NOAEC of 2 mg/m³ from the NTP inhalation studies in mice and rats was identified in which non-cancer lung effects, with lung overload, were noted at the next highest concentration of 6 mg/m³.

Using a lower-tier assessment approach, a small margin of exposure (MOE) of 1.5 was obtained through the comparison of the NOAEC of 2 mg/m³ to the average talc air concentration of 1.36 mg/m³ following the use of a loose powder self-care product. Additional refinements were applied taking into consideration the differences in exposure duration between the exposure scenario and the animal study to incorporate into a higher-tier assessment. The NOAEC is derived from an animal study with an exposure duration of 6 hours per day, 5 days per week, over 4 weeks, while the actual exposure scenarios from the use of self-care products are intermittent, occurring in minutes per day, daily, or weekly over many years.

To address this difference, both the NOAEC (2 mg/m³) and the talc air concentration (1.36 mg/m³) were adjusted to a continuous exposure scenario according to U.S. EPA guidance on inhalation risk assessment to more accurately characterize potential risk (U.S. EPA 1994, 2009). The NOAEC of 2 mg/m³ is equivalent to an adjusted concentration of 0.36 mg/m³, as noted in the *Health effects* section. The NOAEC of 2 mg/m³ was extracted from a 4-week inhalation study as a NOAEC for chronic exposure was not available. The measured talc air concentration (1.36 mg/m³) from the use of self-care products was also adjusted to a continuous exposure scenario (higher-tier assessment) as presented in Table 7-3 (for further details see Appendix A, Table A-2). Episodic exposures from product use are expected to increase lung load due to the long alveolar clearance of talc.

Table 7-3. Relevant exposure and hazard values for talc, and margins of exposure, for determination of risk

Exposure scenario	Adjusted air concentration, CA (mg/m ³) ^a	Adjusted critical-effect level (mg/m ³)	Critical health effect endpoint	MOE
Baby powder 100% talc	0.0071	NOAEC[adj]: 0.36	non-cancer lung effects	50
Body powder 100% talc	0.0047	NOAEC[adj]: 0.36	non-cancer lung effects	76
Face powder 100% talc	0.0047	NOAEC[adj]: 0.36	non-cancer lung effects	76
Foot powder 97% talc	0.0034	NOAEC[adj]: 0.36	non-cancer lung effects	106
Dry hair shampoo 100% talc	0.0011	NOAEC[adj]: 0.36	non-cancer lung effects	327

Abbreviations: adj, adjusted; CA, concentration in air per event; MOE, margin of exposure.

^a Measured air concentrations from Anderson et al. (2017) and Rasmussen et al. (2019) (see Table A-1 for details) based on the highest concentration in products. See Table A-2 for details on adjusted air concentrations. For most of these product types, there is a wide range of talc concentrations (< 10% to 100%).

The margins of exposure (MOEs) between the adjusted critical effect level and the adjusted air concentrations range from 50 to 327 for self-care products. The MOEs for baby powder, body powder and loose face powder are considered potentially inadequate to account for uncertainties in the health effects (including the use of a short-term study due to a lack of a NOAEC from chronic studies) and exposure databases. The MOEs for dry hair shampoo and foot powder are considered adequate to address uncertainties in the health effects and exposure databases.

Based on the available data, ovarian cancer was identified as a critical health effect for the perineal route of exposure to talc. While animal models are generally inadequate to assess ovarian cancer risk, the available animal studies (noting inflammatory response to talc and the ability of talc particles to migrate up the reproductive tract) support biological plausibility and results were consistent with a possible human mode of action for cancer development. The database is large, and while cohort and case-control studies generally gave different results, the overall database provides adequate information to assess the risk of ovarian cancer due to talc exposure. There is the potential for perineal exposure to talc from the use of various self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath). Characterization of ovarian cancer risk is qualitative in nature as a clear dose response for ovarian cancer could not be derived from the available literature. Data from meta-analyses of epidemiological studies indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer (Huncharek et al. 2003; Langseth et al. 2008; Terry et al. 2013; Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019). Although some authors note concerns with regard to bias in the literature, considering the available lines of evidence, the current data are indicative of a causal effect. Given that there is the potential for perineal exposure to talc from the use of various self-care products, a potential concern for human health has been identified.

7.4 Uncertainties in evaluation of risk to human health

The inhalation of talc has been associated with a variety of non-cancer lung effects, commonly termed talcosis. Dose-response data for lung effects in humans are, for the most part, lacking, and the use of animal data to quantify risk due to talc inhalation is considered appropriate. Despite the lack of exposure quantification, there are numerous case reports, as well as worker studies, that have identified non-cancer health effects from inhalation of talc powders. As there are no adequate long-term inhalation toxicity studies in animals, there is some uncertainty regarding the extrapolation of the NOAEC identified in animal models exposed for 6 hours per day for a short duration (4 weeks) to

long-term episodic human exposures. The true NOAEC for chronic exposure in test animals is likely substantially lower than 2 mg/m³.

There is some uncertainty in using combined air concentrations from adults applying body powders and adults applying face powder as surrogate data for infants during diapering, adults during diapering, and adults applying foot powder and dry hair shampoo. Aylott et al. (1979) found air concentrations in the breathing zone of infants during diapering to be approximately 10-fold lower than adults during diapering activities. However, in studies conducted by NIOSH (Dement et al. 1972) and Pooley (1972), air concentrations in the breathing zone of infants were similar to, or in some cases higher than, adults who were diapering infants. The best and most relevant available data were used to derive air concentrations of talc during the use of self-care products.

Some self-care products, and in particular some face powders, may contain a cover or another mechanism that could reduce either the potential for the generation of a particle or dust cloud or the concentration of the dust cloud during use of the product. There is uncertainty as to which products on the market, if any, incorporate these exposure-mitigation measures and the proportion of such products.

There is also some uncertainty regarding the use of talc diaper rash products on broken or abraded skin, where talc penetration may occur, in contrast to use on healthy skin. The CIR Expert Panel (2013) concluded that “talc should not be used on skin where the epidermal barrier is removed or on skin that has greater than first degree burns.” However, typical diaper rashes are unlikely to reach the severity described.

Ovarian cancer, in general, is not well understood, and a comparable animal model is not available. The available human studies on possible migration of talc to the ovaries and presence of talc particles in the ovaries are indicative but not definitive. Limitations of these studies include the fact that particles are administered in solution, that particles are inserted into reproductive tract channel, and that the studies are conducted on patients undergoing elective surgery (perhaps under anesthesia, in the supine position and/or not of healthy status). The studies available also did not assess long-term exposure, with most only examining one or a few administrations. In general, there was a lack of studies that investigated long-term perineal talc exposure in a healthy individual.

There are also limitations with the human epidemiological data. There are a range of opinions in the literature as to whether ovarian cancer should be analyzed as a whole or divided into specific subtypes. Information is also lacking with respect to the exposure in the epidemiological studies. The questions asked of participants in the epidemiological studies were not always specific to talc-containing powders, and even when the questions were more detailed, participants may make assumptions or not specifically recall whether they used talc-based formulations. If “users” were actually users of talc-free powders, this could falsely bias results towards the null (Singh 2018; Tran et al.

2019). There is uncertainty as to whether, or how much, bias and confounding may have factored into the cohort and case-control studies. There is also uncertainty around possible selection bias in the epidemiological studies. Both case-control and cohort designs are susceptible to selection bias, which can bias the results in either direction. It is possible that the selection of participants is not representative of the entire target population and/or that the cases versus controls (or exposed versus unexposed) within a study differ from one another. The response rates and exclusion criteria can also contribute to selection bias as it is not known how results would be affected if all potential subjects had actually participated (Singh 2018; Ballman 2019; Merlo 2019; Goodman et al. 2020). While there may not be consensus within the scientific community regarding the interpretation of the epidemiological information, after weighing the available lines of evidence, the assessment determined that the current data are indicative of a causal effect.

It is also possible that the identified cancer incidences are specific to loose powder formulations. However, there is limited information on cancer incidences and other formulation types (e.g., creams). Health Canada has identified self-care products with the potential for perineal exposure (e.g., baby powder, body powders, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), but there is no indication exactly how the products are being used, the extent to which they would contribute to perineal exposure, or with what frequency and amount.

Talc use during diapering has not been adequately addressed in the literature. It has not been determined whether the internal female genital tract is exposed to talc dusts during infancy (Muscat and Huncharek 2008) or how long the insoluble particles may remain in human reproductive tract tissues. This may impact the calculation of risk from case-controlled studies if cases of women who self-identify as “never-users” were in fact exposed as infants through diapering.

Similarly, whether inhalation of talc particles could result in ovarian exposure due to lymphatic transfer of particles or whether responses may be immune-mediated has not been adequately investigated for use in mode of action analysis.

8. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to the environment from talc. It is concluded that talc does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Considering all the information presented in this screening assessment, it is concluded that talc meets the criteria under paragraph 64(c) of CEPA as it is entering or may enter

the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that talc meets one of the criteria set out in section 64 of CEPA. It has also been determined that talc meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

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Appendix A. Inhalation exposure estimates

Table A-1. Respirable air concentrations (mg/m³) as measured in Anderson et al. (2017) and Rasmussen et al. (2019)

Product	Subject	Average respirable concentration (mg/m ³) (% RSD)	Average concentration (mg/m ³) by subject \pm SD (% RSD)	Study
Body powder	1	1.31	1.37 \pm 0.87 (63.26)	Anderson et al. 2017
Body powder	1	0.69	-	Anderson et al. 2017
Body powder	1	2.61	-	Anderson et al. 2017
Body powder	1	0.87	-	Anderson et al. 2017
Body powder	2	5.03	3.28 \pm 1.17 (35.77)	Anderson et al. 2017
Body powder	2	2.7	-	Anderson et al. 2017
Body powder	2	2.76	-	Anderson et al. 2017
Body powder	2	2.61	-	Anderson et al. 2017
Body powder	3	0.35	0.44 \pm 0.18 (39.68)	Anderson et al. 2017
Body powder	3	0.26	-	Anderson et al. 2017
Body powder	3	0.66	-	Anderson et al. 2017
Body powder	3	0.5	-	Anderson et al. 2017
Body powder	4	1.16	0.99 \pm 0.32 (32.20)	Anderson et al. 2017
Body powder	4	1.18	-	Anderson et al. 2017
Body powder	4	NR	-	Anderson et al. 2017
Body powder	4	0.62	-	Anderson et al. 2017
Body powder	5	0.75	1.15 \pm 0.70 (60.62)	Anderson et al. 2017
Body powder	5	0.68	-	Anderson et al. 2017
Body powder	5	2.18	-	Anderson et al. 2017
Body powder	5	1.00	-	Anderson et al. 2017
Body powder	A	0.48	0.48 \pm 0.18	Rasmussen et al. 2019
Face powder	B	1.80	1.80 \pm 0.82	Rasmussen et al. 2019
Overall average	-	1.44 (81.68)	1.36 \pm 0.97 (71.51)	Combined
Range	-	0.26 – 5.03	0.44 – 3.28	Combined

Abbreviations: NR = not reported; mass on filter reported as a negative mass

Table A-2. Estimated inhalation exposure concentrations from self-care products containing loose powder talc available to consumers

Scenario	Talc product conc. ^a	Study ^b conc. (mg/m ³)	Tier 1 CA ^b (mg/m ³)	ET ^c (hr/d)	EF ^d (d/yr)	ED ^e (yr)	Higher tier EC adjusted ^f (mg/m ³)
Baby powder, infants	100%	1.36	1.36	0.125	365	4	0.0071
Baby powder, adults	100%	1.36	1.36	0.125	365	8	0.0071
Body powder, adults	100%	1.36	1.36	0.083	365	68	0.0047
Face powder, adults	100%	1.36	1.36	0.083	365	68	0.0047
Foot powder, adults	97 %	1.36	1.32	0.083	274	68	0.0034

Dry hair shampoo, adults	100 %	1.36	1.36	0.083	84	68	0.0011
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Abbreviations: Conc., concentration; CA, concentration in air per event; ET, exposure time; EF, exposure frequency; ED, exposure duration; EC, adjusted exposure concentration.

^a Highest concentration of talc found per product type from notifications submitted under the *Cosmetic Regulations* to Health Canada for talc, DPD [modified 2018], email from the Therapeutic Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 20, 2017, unreferenced; LNHPD [modified 2018], email from the Non-prescription and Natural Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 20, 2017, unreferenced; Fiume et al. 2015; Household Product Database 1993-; CPCat 2014; CPID 2017; SDS Search Tool 2016.

^b Average by subject from Anderson et al. (2017) and Rasmussen et al. (2019). CA = average study concentration × maximum talc concentration in product.

^c ET is based on the best and most relevant available data. An exposure time of 5 minutes/application is an estimate based on a number of factors including the duration of the particle cloud measured in Rasmussen et al. (2019) (approximately 1 minute), the average sampling duration of 6 minutes from Anderson et al. (2017), the formation of secondary particle clouds as observed in Rasmussen et al. (2019), Pooley (1972), and by NIOSH in an earlier study on talc cosmetic products (Dement et al. 1972). Therefore, there is a need to account for time spent in the vicinity of where the individual is conducting the activity. The median time spent in the bathroom following a shower or bath as reported in U.S. EPA (2011) in Tables 16-29, 16-32, 16-34 and 16-35 ranges from 1 to 10 minutes, with a median time of 5 minutes for the majority of subgroups. The RIVM cosmetic factsheet uses a default of 5 minutes as the typical time spent in a bathroom (U.S. EPA 2011, RIVM 2006). ET = exposure time/application × number of applications/day if there is more than one application per day, whereby baby powder assumes 1.5 applications/day (CTFA 1983, Health Canada 2020); the rest assume 1 application/day or less.

^d EF is based on the best and most relevant available data reviewed by Health Canada. Frequency values were assumed to occur daily (1.5 applications/day) for baby powder (CTFA 1983, U.S. EPA 2011, Health Canada 2020). Higher values were available in the literature, but were considered too high as this use is no longer recommended by the American Academy of Pediatrics (2015). One application per day was considered for body powder (Zazenski et al. 1995; U.S. EPA 2011 [Table 17-3, baby powder, adult use]; Burns et al. 2019; Health Canada 2020). One application per day was considered for face powder (Ficheux et al. 2015 [Zazenski et al. 1995, median frequency for loose powder foundation], Health Canada 2020 [facial make-up foundation – powder]) as this was the highest central tendency value (median) from the highest quality study (Ficheux et al. 2015). Foot powder was estimated to be used 0.75 times/day or 274 times/year (Ficheux et al. 2015, Health Canada 2020) as this was the highest central tendency value from the highest quality study available. Dry hair shampoo was estimated to be used 0.23 times/day or 84 times/year (Ficheux et al. 2015, Health Canada 2020) as this was the highest central tendency value from the highest quality study available.

^e Assumed infant wears diapers up to 4 years, adult exposure to baby powder from diapering children, 4 years per child and assume two children per family (Statistics Canada 2016), adult exposure for body powder, and foot powder (80 years lifetime, 12 years child).

^f Adjusted exposure concentration is calculated in accordance with Equation 8 in the U.S. EPA 2009 guidance document “Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual,” where $EC = (CA \times ET \times EF \times ED)/AT$, and AT = averaging time, which is on the basis of $ED \times 365 \text{ days/year} \times 24 \text{ hours/day}$.

Exhibit 117

Your questions deserve answers.



The talc in Johnson's Baby Powder is the purest, safest pharmaceutical-grade talc on earth. It doesn't contain asbestos and never will. We test every single lot to ensure it.

The FDA has tested Johnson's talc since the '70s and has confirmed - every single time - that it did not contain asbestos.

We have always cooperated fully and openly with the FDA and other regulators and have given them full access to our talc testing results.

We did not hide anything. Ever. Our openness and collaboration with the FDA and regulatory agencies is well documented.

We have always acted with the utmost transparency in this matter. Nothing is more important to us than the health and safety of our customers. We're parents and grandparents, just like you. If we had any reason to believe our talc was unsafe, it would be off our shelves immediately.

There is irrefutable scientific evidence that our talc is safe and beneficial to use. Go to factsabouttalc.com. There you'll find independent studies from leading universities, research from medical journals, and third-party opinions, so you can learn the facts and make up your own mind.

Johnson & Johnson

Exhibit 118

Since 1920...Johnson's Baby Powder

the best you can buy...the purest, smoothest,
most absorbent, has the nicest perfume

Why reach for anything less
than Johnson's...best for baby...best for you





Let our family take loving care of yours.

Remember when your mother took care of you with JOHNSON's baby products? How good it made you feel? Well, you can feel that way again. You, and those you love.

Everyone, including the man of the house, will enjoy the fresh, clean feeling of pure JOHNSON's Baby Powder.

And thick, rich JOHNSON's Baby Lotion will help keep the whole family feeling soft and smooth. So they won't have to worry about the kind of dryness that shows.



JOHNSON's Baby Shampoo cares for your entire family with a trusted "No More Tears"™ formula that cleans hair gently, leaving it healthy-looking with a natural sheen.

JOHNSON's Baby Oil not only helps take care of your baby in lots of ways. It also works in many ways as a beauty oil for you.

Our JOHNSON's baby products have helped take care of families for almost fifty years. And we can help take loving care of yours.

Johnson & Johnson

Since 1920...Johnson's Baby Powder
the best you can buy...the purest, smoothest,
most absorbent, has the nicest perfume

Why reach for anything less
than Johnson's...best for baby...best for you



Exhibit 119

'97-09-18 00:34 A.P.

P.1

ALFRED P. WEHNER, D.M.D., Sc.D., CAND. MED.
DIPLOMATE, ACADEMY OF TOXICOLOGICAL SCIENCES
312 SAINT STREET
RICHLAND, WASHINGTON 99352

9/17/97

Mr. Michael R. Chudkowski
Manager, Preclinical Toxicology
J&J Consumer Products, Inc.
Skillman, NJ 08558-9418

Dear Mike:

There is a German saying which translates as follows:

"A true friend is not he who beguiles you with flattery
but he who discloses to you your mistakes
before your enemies discover them."

In this spirit I would like to volunteer a critique of the three CTFA response statements which you faxed me on September 11. Some of the wording leaves CTFA wide open to counter-attack. The most harmless response statement of the three is the one dated July 1, 1992. It does not give the names of the authors and the title of the paper to which the response is being made. More important, I believe that different and/or additional more powerful statements along the lines of my critique faxed to Jerry McEwen, as far as applicable to the situation in 1992, would have put CTFA in a more advantageous tactical position. Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not trans-late (sic!) through the cervix to the uterine cavity and beyond" does not address the problem, does not refute these findings, and therefore does not serve CTFA's best interest. All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk." This statement is outright false. All an Epstein, a Kennedy, or one of their aides knowledgeable in matters talc, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0873 Fax 509/375-5693

Plaintiff's Exhibit
No.

P-20

J&J-0115053

'97-09-18 00:35 A.P.

P.2

Here, too, I believe that more powerful and better defensible arguments could and should have been made on behalf of the industry.

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper, Debra Heller, and others. What the workshop panel did conclude was that (1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconclusive, (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments (plus some of those along the lines of my fax to Rich) instead of questionable mush that leaves one vulnerable to counterattack? The following sentence states: "In addition there is no basis to conclude that talc is capable of migrating to the ovaries...". I submit that several reports, independently describing talc particles in/on ovarian tissue, along with other suggestive evidence (questionable as some of it might be) does provide a basis for just such a conclusion. My point is that such a complex and vexing issue cannot be credibly dismissed with one sweeping statement without any documenting references.

Mike, I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent. As a consultant on a retainer I feel obligated to proactively act in the best interest of my client at all times, not only when I am approached with a specific assignment. This consideration alone motivated me to spend the time to bring my thoughts on this matter to your attention. I trust that in the process I did not step on anybody's toes.

Best regards

AL

J&J-0115054

Exhibit 120

C·T·F·A

Representing the personal care products industry

*E. Edward Kavanaugh
President*

DRAFT MINUTES

TALC INTERESTED PARTY TASK FORCE

CTFA
Main Conference Room
1101 17th Street, N.W., Suite 300
Washington, DC 20036

Plaintiff's Exhibit
No.

P-14

July 21, 1993

A meeting of the Talc Interested Party Task Force was held at CTFA on Wednesday, July 21, 1993 beginning at 10:00 a.m. Those in attendance were:

Dr. Laureen MacEachern - COLGATE-PALMOLIVE
Ms. Kate Trammell - MAYBELLINE
Mr. William Ashton - JOHNSON & JOHNSON (Guest)
Mr. Mike Chudkowski - JOHNSON & JOHNSON
Mr. Richard Zazenski - LUZENAC AMERICA
Dr. Martin Roddy - NOXELL
Ms. Marjorie McTernan - JOHNSON & JOHNSON (Guest)
Dr. Stephen Gettings - CTFA (Liaison)

I. OPENING REMARKS

1. SGettings opened the meeting and apologized for calling it at such short notice. He noted that the purpose of the meeting was to discuss the outcome of a meeting SGettings held with members of the Planning Committee of the International Society of Regulatory Toxicology & Pharmacology (IS RTP), held at the ToxForum meeting on July 14th, 1993. The minutes of the last meeting were approved with no changes.

II. INFORMATION EXCHANGE/GENERAL DISCUSSION

1. SGettings noted that ISTRP have been asked by FDA to organize a 1-2 day symposium on talc safety and related issues (93-TA-10). The Task Force was alerted as to this possibility in February, 1993 (93-TA-07).
2. At the IS RTP Planning Committee meeting SGettings was

*The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, N.W. • Suite 300 • Washington, D.C. 20036-4702 • (202) 331-1770 • Fax (202) 331-1969*

apprised of the following:

The intended target audience are regulatory specialists, toxicologists, food/drug/cosmetic/medical device manufacturers, academicians and medical professionals. At least 100 attendees are anticipated.

From the meeting, FDA hope to gain insight into the relevance of recent toxicological and epidemiological studies to the safety of regulated products. FDA would like participants to address not only the validity of experimental approach but also risk "under conditions of use." FDA does not anticipate that they will be able to develop a regulatory decision from this program alone.

The meeting will be held in the Washington, DC area, possibly at the NIH auditorium. It will be scheduled for late fall (probably November) or for early 1994 (January).

The symposium will relate principally to ingredient use and safety as it applies to consumer products. (FDA anticipate that scientific studies relating to occupational uses of talc will contribute to the program as it relates to consumer products). Relative to OTC drug use of talc, FDA feel that someone from USP should at least serve on the panel for discussion and possibly make a presentation on USP specifications. Apparently, the OTC group thinks there should be a discussion of product labeling as it applies to OTC products, i.e., diaper rash could be discussed for adequacy and possible suggestions. FDA feel that this portion of the program would be useful in assessing whether or not the current USP specifications are adequate.

The proceedings of the symposium will probably be published (probably as a meeting summary, by rapporteurs).

FDA is budgeting \$10,000 as financial contribution to the effort; industry has been asked to contribute \$20,000; the remainder will be provided by IS RTP.

The anticipated format is to have some sort of "expert panel" in attendance throughout the meeting. FDA suggest that someone from industry (possibly a member of the CIR Expert Panel) and a consumer representative be invited to sit on the panel. Following the presentations, FDA would like to have ample time for discussions from the floor. The discussion will be led by members of the panel.

3. The following agenda has been proposed following discussions between IS RTP and FDA:

DAY 1 - The first day of the symposium will concentrate on inhalation health considerations, and will take the following format:

Introduction - introduce the topic, present the reasons for holding the symposium and provide some background about studies conducted on the safety of talc (historical perspective). IS RTP have been asked to identify someone who can serve in this capacity.

Manufacture of talc - To discuss (1) how, and where, it is obtained (mineral sources), (2) specifications for talc as used in different products, and (3) quality control including steps to control and monitor asbestos contamination. FDA stress that it is important for this presentation to describe the "specifications" for the material that is actually used in different products (i.e., particle size, impurities, etc). CTFA has been asked to identify a suitable speaker.

Uses of talc in different FDA-regulated products - Specifically, what are the requirements for the use of talc in foods, drugs, cosmetics and medical devices and why they are critical. (FDA suggest that this presentation may be combined with the previous one).

Regulatory status of talc in the different product categories - This topic will be discussed by one (or more) FDA officials.

Health Perspectives - Presentation and critique of the NTP inhalation study by various presenters (eg., Oberdorster, Goodman etc).

Panel/Floor discussion

DAY 2 - The second day will primarily cover ovarian cancer and talc, but epidermatology as it relates to inhalation exposure with will also be discussed.

Introduction - historical overview of the various epidemiology studies on talc (possibly in 2 parts):

- a. Epidemiology studies of occupational exposures (inhalation).
- b. Epidemiology studies on ovarian cancer.

Risk factors in ovarian cancer

Harlow's Epidemiology studies of ovarian cancer and perineal exposure.

Meta-Analysis - Discussion of the pros and cons of meta-analysis as a general statistical tool in measuring correlations in epidemiology studies.

Panel/Floor discussion

Moderator wrap-up and close

III. ACTION/NEXT STEPS

1. The Task Force agreed that it was clear that the ISTRP meeting will be held irrespective of industry input, but that such input was important. The Task Force agreed that it was important that, as industry's representative, SGettings continue to participate at the ISRTP Planning Committee meetings and to offer advice and suggestions as outlined by the Task Force.
2. The Task Force agreed that the level of sponsorship requested by industry was not prohibitive. CTFA will send out commitment forms requesting total sponsorship from the Task Force of \$20,000 (depending upon the number of participants, as low as \$1,000 per company).
3. The Task Force agreed that Dr. Bruce Semple (formerly of J&J, now with P&G) should be approached and asked to represent industry on the Panel (both days of the meeting).
4. The Task Force agreed that a representative of one of the talc suppliers should make a presentation on (1) the production, processing and quality control of talc manufacturer; and (2) particle size and specifications for different product applications. RZazenski agreed to provide a presentation outline and a suggested speaker within the next few days. The Task Force agreed that all speakers will be representing the industry and that the Task Force will approve the contact of each industry presentation.
5. The Task Force agreed that a representative of a finished-product manufacturers should make a presentation on consumer use/risk assessment of cosmetic products containing talc. SGettings will get clarification on whether other speakers will address similar issues as they relate to other talc uses. The Task Force suggested that BSemple would again be the most appropriate industry representative. The Task Force agreed to begin assembling data which might form the basis of such a presentation. It was noted that some of this information (on particle size and product notices) had previously been requested by FDA and that the Task Force had not been successful in collecting such information. WAShton

agreed to review, in particular, J&J's published data on exposure to talc. RZazenski noted that a lot of useful information could be derived from the report prepared by JKalse for the Task Force. LMacEachern noted the presentation should reference recent studies on talc (93-TA-12). LMacEachern noted that the presentation should emphasize the safety of talc use.

6. The Task Force agreed to review available information on occupational exposure from inhalation, and to discuss this issue at a follow-up meeting.
7. The Task Force agreed that both Dr. Oberdorster and Dr. Wehner (both co-authors of the BEC Report) should be proposed as speakers (on lung overload mechanisms and the biological implausibility of ovarian cancer from talc exposure, respectively). The Task Force agreed that industry should arrange for their attendance (at cost), even if they are not selected as speakers. It was also suggested that the Task Force may wish to arrange for the attendance of other consultants if necessary.

IV. ADJOURNMENT/NEXT MEETING

1. It was noted that SGettings next meets with ISRTP in early August. The Task Force agreed to hold a follow-up conference call within the next few days and to arrange a Task Force meeting in early September.
2. There being no further business, the meeting was adjourned.

Respectfully submitted,

Formulate Question/Answers regarding anything on talc
Stephen D. Gettings, Ph.D., D.A.B.T.
CTFA

IAEC - inadequate evidence to show carcinogenicity

— literature survey — publication —

ISRP - Industry Friendly

Exposure data into presentation - Consumer Use

Spoke question from panel or audience. Need experts to address questions.
Langer - IAEC comm. Brooklyn Coll.

— JWRs for search

— Press release summary —

— Mack Ross (Hazardous Survey)

Silica - issue cosmetic talc (B.P.) that contain crystalline silica that (0.1%) that is a carcinogen. Industrial use - labeling req't if > 0.1% silica concentration.

Exhibit 121



FEB 13 '98 02:37PM CTFR1

P.1/3

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

MEMORANDUM

E. EDWARD KAVANAUGH
P R E S I D E N T

DATE: February 13, 1998
TO: TALC INTERESTED PARTY TASK FORCE
FROM: Pandora Dennis
Administrative Assistant - Science

Please deliver this and the following page(s) to the corresponding individual in your company.
Thank you.

Ms. Debra Ambrose/POLAR MINERALS/(812) 838-4744
Mr. William Ashton/JOHNSON & JOHNSON/(908) 874-1254
Ms. Donna Beach/COSMAIR/(908) 499-2929
Dr. Daniel Briggs/PROCTER & GAMBLE/(513) 626-4399
Mr. Michael Chudkowski/JOHNSON & JOHNSON/(908) 874-1254
Mr. Shawn Hays/POLAR MINTERALS/(404) 934-4376
Dr. John Hopkins/JOHNSON & JOHNSON/(908) 874-1155
Mr. Daniel Johnson/COMBE INCORPORATED/(914) 694-1585
Mr. John Kelse/RT VANDERBILT COMPANY/(203) 853-1452
Mr. Louis Kotyuk/WHITTAKER, CLARK & DANIELS/(800) 833-8139
Mr. Mike Larson/MINERALS TECHNOLOGIES/(212) 878-1804
Dr. Laurie Pan/MARY KAY COSMETICS/(214) 905-6799
Dr. Steve Pennisi/COMBE INCORPORATED/(914) 694-1585
Mr. Thomas Pallone/ALBERTO-CULVER/(708) 450-3067
Dr. Thomas Re/BRISTOL-MYERS/(908) 851-6250
Ms. Janice Rogers/GILLETTE/(301) 590-1535
Dr. Bruce Semple/PROCTER & GAMBLE/(513) 626-2977
Dr. Tracey Spriggs/COLGATE-PALMOLIVE/(908) 878-7844
Ms. Elaine Stern/HELENE CURTIS/(312) 384-3539
Ms. Joan Thomas/CTPA/(011) 441714938061
Dr. Maureen Toulon/AVON/(914) 369-2898
Mr. Richard Zazenski/LUZENAC AMERICA/(303) 643-0446

HA\SCIENCE\LU\DATA\WP\DOC\TALC\FAXCOVER.2

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702
202.331.1770 FAX 202.331.1969
<http://www.ctfa.org>
SECURING THE INDUSTRY'S FUTURE SINCE 1894

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Plaintiff's Exhibit
No.
P-83

LUZ011963

Exhibit 122



TITLE: Talc IP - Revenue Received
 GENERAL LEDGER ACCOUNT: #25078
 DATE INITIATED: 08/17/92

PARTICIPANTS:	1992	1993	1994	1997	2000	2001	2005	2008	2009	Total
Alberto-Culver				500						500
Avon Products	5,000	2,000	894		10,000	2,000				19,894
Bristol-Myers / Clairol				500	6,000	1,500				8,000
Carter-Wallace, Inc.	5,000									5,000
Colgate-Palmolive	5,000	2,000	894	500						8,394
Combe Inc.				500						500
Cosmair, Inc.	5,000	1,500	894	500	1,000					8,894
Estee Lauder, Inc.	5,000									5,000
Helene Curtis / Unilever	5,000	1,500	894	500	31,000	6,500				45,394
Johnson & Johnson	5,000	2,000	9,310	500	151,000	7,500	15,000			190,310
L'Oreal					10,000	2,500			2,500	15,000
Luzenac America	5,000	2,000	894	500	31,000	7,500			2,500	49,394
Mary Kay Cosmetics	5,000	1,000	894	500	1,000	500				8,894
Maybelline, Inc.	5,000	1,500	894							7,394
Pfizer/Minterals Tech.	5,000	1,500	1,126	500		500				8,626
Polar Minerals				500	1,000	500				2,000
Procter & Gamble (incl Noxell)	5,000	2,000	894	500	1,000					9,394
Schering-Plough Corp.	5,000	1,500	894							7,394
US Cosmetics Corp.	5,000			500						5,500
R. T. Vanderbilt	5,000	1,500	894	500	1,000					8,894
Whittaker, Clark & Dan.	5,000	1,000	894	500	1,000					8,394
American Westmin	5,000	1,000	894							6,894
Mary Kay Cosmetics								2,500		2,500
Procter & Gamble								2,500		2,500
Revlon								2,500		2,500
The Dial Corp									2,500	2,500
	85,000.00	22,000.00	21,164.00	7,500.00	245,000.00	29,000.00	15,000.00	7,500.00	7,500.00	439,664.00

Exhibit 123

Luzenac America

Profile

- 4 Talc Mines & 8 Mills in North America
- 500,000 TPY
- \$85 MM Sales
- Primary Markets
 - Paper
 - Polymers
 - Paint & Coatings
 - Personal Care (i.e. J&J Baby Powder)

-1

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LUZ022044

1 of 7

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Regulatory Issue

National Toxicology Program (NTP)

- Coordinates Interagency Toxicological Testing
- Publishes Report on Carcinogens (RoC)
- Minimal Threshold for Carcinogenic Listing
- Listing Triggers OSHA and Prop 65 Labeling
- Conducted Talc Inhalation Study on Rodents
- Nominated Talc for Review in 2000

-2

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LUZ022045

NTP Listing Consequences

- Immediate Loss of Personal Care Market
 - \$10,000,000 in Year 1
- Deterioration of all Markets due to Labeling
 - 20 to 50% of remaining sales year 3
- Regulated as a Carcinogen Worldwide
- Talc Litigation likely to Proliferate

Talc Health Issues

- Risk Factor in Ovarian Cancer
 - Perineal dusting by women
 - No causal explanation
- 1992 NTP Rodent Study
 - Lung tumors in female rats
 - Lung overload phenomenon
- Association with Asbestos
 - Long-held public perception
 - Chemical similarity

NTP Talc Review Summary

- Review Group 1 voted 6-1 *to List* Talc
 - Cited ovarian studies and NTP Rodent study
- Review Group 2 voted 7-1 *to List* Talc
 - Cited ovarian studies and NTP Rodent study
- BSC Subcommittee Voted 7-3 *Not to List* Talc
 - Influenced by industry comments and criticisms of NTP Report on Talc
- NTP Exe. Committee Defers Vote on Talc
 - Remands issue back to NTP reviewers

Luzenac Defense Strategies

- Unite Behind the Cosmetic, Toiletry & Fragrance Association (CTFA)
- Engage Services of the "Center for Regulatory Effectiveness (CRE)"
- Aggressive Corporate Position

OUTLOOK

- Deferral Due to "Fatal Flaws" in Draft Report
- Temporary "Reprieve" for 2-3 Years
- Insist Upon the Need for Additional Studies
- Updates on Gertig et al. Study of 76,630 U.S. Women - No Increased Risk with Talc Usage
- Re-examine Prior Epidemiology Studies - Negative Dose Response?
- IARC Re-examination of Talc a Possibility

Exhibit 124

C · T · F · A

Representing the personal care products industry

92-SE-328

92-SAC-24

E. Edward Kavanaugh
President

MEMORANDUM

TO: Scientific Advisory Committee

FROM: G.N. McEwen, Jr., Ph.D., J.D.
Vice President - Science

DATE: July 17, 1992

SUBJ: TALC SAFETY INTERESTED PARTY

The conclusions in two recent studies question the safety of cosmetic grade talc. A draft report of one study, involving daily, lifetime inhalation of massive amounts of talc in rats and mice, concludes there is clear evidence that talc is a carcinogen for female rats, and some evidence that it is a carcinogen for male rats. There was no evidence of carcinogenicity in male or female mice. The other study concludes that there is an association between talc use in the perineal area and ovarian cancer in women. CTFA will provide copies of these reports upon request.

Although CTFA is convinced that these studies do not suggest any hazard from normal use or foreseeable misuse of personal-care products or cosmetics containing talc, such reports may have wide implications for classification and characterization of talc by various regulatory agencies, including OSHA, FDA, and California's Office of Environmental Health Hazard Assessment, responsible for listing substances for Proposition 65.

CTFA has instituted an Interested Party Task Force to address these studies. The Task Force is developing a strategy to defend the continued safe use of talc, and is open to those companies willing to provide financial support for this activity. For further information on how to join the Task Force, please contact Dr. Stephen Gettings, Director, Toxicology, CTFA.

GNM/pcl
cc: Scientific Advisory
Executive Committee

The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, N.W. • Suite 300 • Washington, D.C. 20036 • (202) 331-1770 • Fax (202) 331-1969

Plaintiff's Exhibit
No.

P-122

Exhibit 125

CALL REPORT
Luzenac America

Date: 11/8/93 Regional Manager: J. A. Tracy
Date of Call: 11/8/93 Accompanied By: _____

Cust Name: Carter Wallace Cust#: 05258/0000
City & State: Trenton, NJ Industry Code: 05:001
Contacts: Deborah Richardson, Purchasing Agent

Prod#: 11234 Descrip: Vertal 1500USP Qty: 200TPY Price: _____

Comp#1: DeGussa Prod: Hydrated silica Qty: _____ Price: _____
Comp#2: _____ Prod: _____ Qty: _____ Price: _____

PRODUCT APPLICATION: Dusting of latex rubber condoms.

OBJECTIVE: Find out the status of the replacement of talc, and discuss the Johnson plant closing.

SUMMARY: Debbie said that they have switched from talc to hydrated silica that they get from DeGussa. Huber is another approved supplier. She said that the silica is so light and fluffy that they have built a closed dusting system to contain the dust. I asked her if they were not concerned about the use of silica. She said they were, but felt that the only problem was with respirable silica. Their closed system they feel is sufficient protection for their workers.

She said that they were pleased with the performance of talc, but were concerned because a CTFA report in July 1992 said that there was suspicion that talc could cause ovarian cancer. Although the report didn't say that it was a cause, Carter Wallace is concerned about future litigation.

Debbie said that if silica becomes a problem, they might look at talc again.

ACTION REQUIRED: No action required.

Exhibit 126

January 2, 2002

Principal Argument for Adopting Luzenac America's NTP Strategy

We engaged the council of the Center for Regulatory Effectiveness ("CRE") in November 2000 for the purpose of providing us direct assistance in developing a business strategy to challenge the NTP talc review. CRE 'knows' NTP. CRE knows many of the individuals personally – most importantly, the key decision-makers. They know how NTP operates, both technically and politically. CRE knows how NTP 'values' the significance of published human and animal studies. CRE knows the influential people from the other agencies who get involved in the review process. Simply put, CRE possesses the knowledge and experience to help us effectively mount a strategic challenge to the NTP talc review.

From the beginning, CRE has recommended that we adopt an aggressive (professional) approach with NTP. Our technical (and legal) arguments have alternated between Luzenac and CRE letterhead - designed to maximize the intended effect.

Presently, CRE believes the request for by Dr. Olden (NTP Director) presents us with an opportunity to 'proactively' submit a detailed literature research paper that not only directly addresses the unresolved issues (mineralogy), but also other controversial issues that we anticipate will (or should) resurface (epidemiology, causation, consistency of results). It affords us the opportunity to initiate the agenda for discussions with NTP.

To reject their recommendations in this important process would be unwise.

For the Record

In November 2000, Luzenac discovered the "fatal flaw" in the NTP report. With the help of CRE we exploited this issue with NTP which ended in the deferral decision by the NTP Executive Committee.

The public record will reflect that Luzenac America was the only talc-interested-party who recognized this fatal flaw (and winning strategy).

Meli to NTP; Nov. 30, 2000

"A critical error in the fundamental logic of the NTP's own line of argument **categorically invalidates the NTP conclusion**....proposed by RG1 and RG2 that "Talc not containing asbestiform fibers is reasonably anticipated to be a human carcinogen."

'It is also recommended that the Board of Scientific Counselors Subcommittee notify Review Groups 1 & 2 that their conclusion relative to talc not containing asbestos fibers is not supported by the data. The arguments and assumptions made by the reviewers in the text of the Draft Background Document **unquestionably contradict their own conclusion**..."

"It is clear that the premise on which NTP has assessed the literature and safety issues relating to all forms of talc is **seriously faulted and cannot be used** as a reasonable basis for nomination as an anticipated human carcinogen."

Harris to NTP; May 1, 2001

"...and if they (RG1 and RG2 recommendations) were to be submitted to the Director of NTP and the Secretary as valid recommendations, a final decision to list talc not containing asbestiform fibers in the Report would be **arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law, and would be set aside by the Federal courts** pursuant to the Administrative Procedure Act."

.....

KEY POINTS

1. Joachim Roeser must understand that it was the strategy and actions of Luzenac America (not Luzenac Group or Eurotalc) that led to the talc deferral decision (in order for him to respect our current recommendations). Inexplicably, despite the soundness of our strategy, Luzenac Group repeatedly opposed our intended actions throughout the process.
2. CTFA and the talc interested parties have been minimally effective during this NTP review. It is a management problem. They have not demonstrated the leadership necessary to coordinate a diligent, on-going defense of talc. In the spirit of "Either lead, follow, or get out of the way", I recommend Luzenac America (with "CRE") advance our agenda with an invitation to others to follow. I do not favor the "committee approach" to NTP where no one is formally in charge.
3. I am not at all concerned about angering CTFA or any of its members who might be customers. With our entire business literally at stake, we have the "standing" to do what we feel is necessary in this battle for survival. As an aside, only J&J and possibly one other company expressed interest in further funding of the consultants utilized by CTFA last December.
4. We have every right to employ scientific reasoning and logic to the evaluation of health studies involving talc (outside of mineralogy issues). If we bring to light questionable conclusions or flaws in a published study, other experts can then be asked to forward their opinions on the issues. At a minimum, the NTP reviewers would be obligated to discuss and debate our points of contention (e.g., talc detected in ovarian tissue).

Exhibit 127

NARRATIVE
TALC – NTP REGULATORY CHALLENGE

Good morning everyone. My name is Steve Jarvis and I am responsible for Health, Safety, and Environmental matters for Luzenac America.

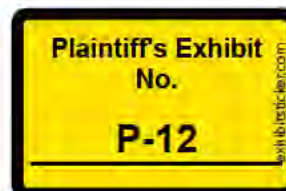
This morning...it is my distinct pleasure to present to you a summary of our most recent regulatory challenge involving the National Toxicology Program and their review of talc for potential listing in the 10th Report on Carcinogens.

But first....for those who may not know exactly what we doI'd like to introduce you to Luzenac America.

SLIDE 1

Luzenac America is part of the Luzenac Group of Companies. Headquartered in France, Luzenac Group is the world largest commercial producer of talc products.

In North America..... Luzenac America operates 4 talc mines and 8 talc milling operations.....We have large operations based in Ontario, Vermont, and Montana. Luzenac America is



headquartered in Denver Colorado where we also have our Research and Development Center.

Luzenac America mines and processes around a half-a-million tons per year generating approximately ^{Redacted} in sales.

Our major markets are talc sales to paper, polymers and paint markets..... and to a lesser degree, personal care products.....

You might be interested to know that we produce all the baby powder for Johnson & Johnson – including the talc for their popular adult product, Shower-to-Shower. As an interesting aside, would you believe that Luzenac talc also goes into Cipro?? It's True!.....

SLIDE 2

Our major regulatory challenge..... a challenge I might add that Luzenac absolutely could not afford to losecame from the NTP.

The NTP was authorized by the United States Congress to coordinate interagency toxicological testing and to publish the formal "Report on Carcinogens" which comes out about every 18-24 months..... To be listed in the RoC can be

devastating to a substance because of mandatory labeling requirements by OSHA and Proposition 65 in California.

In early 2000, NTP nominated talc for possible listing in the RoC because back in the early 1990's, the NTP published the results of a 2-year talc inhalation study on rats and mice and concluded that talc caused lung tumors in female rats.....

More on that in a minute.

SLIDE 3

A listing of talc in the RoC would have devastating consequences for the talc market worldwide.

First of all.....we would see a virtual immediate loss of our sales to the personal care market – around \$10 Million in sales in the first year.

Secondly.....because of the carcinogenic labeling requirements, we would likely suffer a deterioration of sales in all markets....perhaps anywhere from 20% to 50% of all remaining sales by year-three.

Additionally, a listing in the U.S. by NTP would likely trigger a carcinogenic status for talc in Europe and the Far East.

And finally..... because of our consumer product exposure, civil litigation would likely skyrocket.

As I mentioned, simply devastating consequences.

SLIDE 4

Now realistically..... there are some health issues with talc. For nearly 20 years, epidemiologists have been finding a weak, but persistent statistical link between the hygienic use of talc and ovarian cancer. However..... the studies are weakened by no one being able to offer any feasible “causal” explanations as to how and why talc would cause ovarian cancer.....but not a multitude of other cancers in the human anatomy.

As I mentioned, there is the 1992 rodent study by NTP, which found lung tumors in female rats. However, many other leading experts discount this finding claiming the tumors were a result of lung overload - simply too much inert dust in the lungs triggering an traumatic auto-immune response from the rats.

And finally, there is the long-held public perception that all talc contains asbestos. And even if it

doesn't, they are so similar chemically, that talc probably behaves like asbestos.

So these are some of the primary issues and concerns that served as the backdrop for the NTP review.

SLIDE 5

Okay....so here's what happened.

NTP announces in early 2000 that talc is going to be review. While this announcement catches us off guard, we are not alarmed.

But then, in October of 2000, NTP issues their draft report on talc and announces that the first two formal reviews resulted in votes to list talc as a carcinogen. The combined vote was 13-2 to list.

The entire talc industry, as well as companies like J&J were absolutely, positively, unquestionably, flabbergasted..... We simply could not believe it.

But now we had only two months to prepare for the third NTP review meeting..... a public meeting of the influential Board of Scientific Counselors Subcommittee. This occurred in December of last

year and we achieved a very dramatic turnaround. The BSC subcommittee voted 7-3 **not** to list talc.

And finally.....we fast-forward to this past June for the fourth and final review process. We see the NTP Executive Committee took the unprecedented action to actually **“stop”** the review process on talc and send it back to the beginning. They did this by deferring a final vote on talc.

And make no mistake about it, they knew if they proceeded with a listing nomination for talc, Luzenac America was going to challenge them in Federal Court.....and as the facts lay out, NTP would likely lose. Of that we are fairly certain!

SLIDE 6

Our successful defense strategy was threefold.

First.....we continued to work through the auspices of the CTFA – the Washington based trade association for the cosmetics industry. As you might imagine, Luzenac and Johnson & Johnson wield considerable influence on the talc subcommittee.

Secondly.....and this was our secret weapon, engage the services of the Washington based

Center for Regulatory Effectiveness, CRE. Since its formation in 1996 by several ex-high ranking officials in the OMB, CRE has grown into a nationally recognized...and relatively respected... regulatory watchdog organization. Federal agencies frequently come to them for assistance. CRE has also taken NTP to court.

And thirdly, we decided to be aggressive. This was a fight we simply could not lose. As such, we retained expert legal counsel to ensure we would have a solid foundation for a legal challenge if necessary.....it was the same firm which assisted CRE in their court battle with NTP.....and we also became very aggressive in our communication with NTP and other federal agencies. When didn't let the windows of "formal comment periods" become restrictive. We sent e-mails, faxes, overnight letters, and even telephones calls to key players in this battle....right up until hours before the final Executive Committee meeting.

And we believe these strategies paid-off.

SLIDE 7

While we certainly would have preferred a total victory – where NTP declared talc was not a human carcinogen.....we were relieved to at least get the review process “derailed” for now.....at least we have some “breathing space” to prepare a thorough, scientific defense of talc.

One of the issues we plan to focus on is demonstrating to NTP that virtually all of the epidemiology studies they previously used must be declared invalid for use in assessing talc “not containing asbestos”. This will be an expansion of the “Fatal Flaw” defense Luzenac employed in the first review on talc.

Additionally, we believe the latest epidemiology study which IS valid with regard to talc quality....it’s called the Gertig study.....and which also happens to be the largest study as well..... shows no increased risk of ovarian cancer. The significance of this study must be more heavily weighted than prior studies.

Any predictions at this point? Hard to say...but our hard fought victory this past year has given us some confidence and direction.

One last point.....lest we get complacent..
.....regardless of what happens with NTP, we
also have to keep an eye out for IARC. IARC
reviewed talc back in 1986 and concluded there
was insufficient evidence of talc carcinogenicity in
humans. We are hoping that this NTP activity
doesn't stimulate IARC conduct an "end-run"
around NTP declare talc a possible human
carcinogen.....because I think you all know,
we do not have the ability to become an active
participant in that relatively "closed" process.

Thank you for your time.

Exhibit 128

MAR. 26. 2002 7:38AM LUZENAC

NO. 610 P. 1



Luzenac AMERICA

DENVER TECHNICAL CENTER
8985 E. NICHOLS AVE. • ENGLEWOOD, CO 80112 • USA

FACSIMILE

DATE: March 26, 2002	FROM: Richard J. Zazanski Director Product Safety
TO: Bill Ashton J&J	PHONE: 303-643-0404
	e-MAIL: rzazensk@luzenac.com
	FAX: 303-799-8926
cc:	Number of Pages: 13 pages (including Cover Sheet)

CONFIDENTIAL

Redacted



Luzenac GROUP



Redacted

One other note – We've been successful thus far in fending off the NTP classification of talc as being a potential human carcinogen. But we must also keep an eye out for IARC. If they decide to re-review the status of talc because of all the ovarian epidemiology studies that have been published **since 1986**, IARC can surprise us all and decide to list "talc" as a potential human carcinogen. IARC reviews are not a public debate. Unlike NTP, IARC is answerable to no one politically (they are headquartered in Lyon, France of all places). As part of the World Health Organization, they act very independently to protect the citizens of this planet from "preventable" diseases. Their threshold for required medical evidence is predictably quite minimal.

You might want to counsel your management on this potential (and not to be too complacent about the status of talc).

Attached with this fax:

- 1 page on IARC (who they are).
- 2 pages on IARC's 1986 review of talc.
- 8 pages on their 1996 re-review of all forms of silica.

If any pages are unclear, please contact us.



HP OfficeJet G Series G85
Personal Printer/Fax/Copier/Scanner

Fax-History Report for
TECHNICAL ASSURANCE
(908)874-1126
Mar 26 2002 8:16am

Last Fax

<u>Date</u>	<u>Time</u>	<u>Type</u>	<u>Identification</u>	<u>Duration</u>	<u>Pages</u>	<u>Result</u>
Mar 26	8:15am	Sent	918593924202	1:06	1	OK

Result:

OK - black and white fax
Okay color - color fax

Exhibit 129



INTEROFFICE MEMORANDUM

DATE: September 12, 2000
TO: R. Bernstein; J. Gauntt; R. Meli
CC:
FROM: Carl E. Kollmar
SUBJECT: Cosmetics Consultant Update

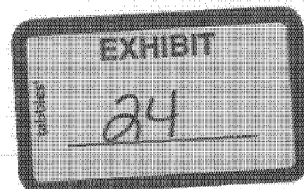
Richard Dodwell has filed his Progress Report. At this stage of the project he has completed all fax and telephone surveys and interviewed Luzenac's salespeople. At this time, there appears to be two problems with the market survey. First, several major body powder players have chosen not to respond to the surveys. This is an issue we need to consider. Second, Luzenac's major cosmetics distributor, WC&D, has not been interviewed. This is because Tom Grunstra, their in-house talc expert, has been out sick for several weeks.

Although we are missing input from several major players, I think there are some basic facts coming to light:

- Health is an issue to large body powder customers - a non-issue in other segments.
- The large volume body powder segment is not growing, although the decline of the past few years appears to have bottomed out. There is some growth in other segments.
- Other than soap bars, there appear to be limited growth opportunities (new markets/new products) for talc.

In my opinion, the large volume body powder portion of this business is not growing, it is price sensitive, there is aggressive competition (supplier and customer) and the oner of health concerns/liabilities hangs over it. This does not appear to be a market of opportunity for Luzenac at this time. Opportunities for growth appear to be limited to the soap bar segment - but the health/liability concerns remain.

In the details of Dodwell's report he identifies six major areas of interest: customer concerns, market growth, pricing, health concerns, competition and responsiveness to the survey.



Protected Document - Subject to Protective Order

LUZ006507

Customer Concerns

There are three major concerns expressed by customers:

- The closing of a Montana mine has caused some disruption in the market. I assume they are referring to the closing of the Beaverhead Mine and the subsequent discontinuance of the Supreme and Olympic products. Some customers are still using old stockpiled material and have either not found or tested a suitable alternate.
- The technical service from Luzenac has declined, but the rest of the service package (quality, delivery, etc.) is well regarded.
- The health issue is taken seriously by large users (mainly body powder customers), and mostly ignored by the smaller segments and packagers.

Market Growth

- The market is growing in many sectors, but remaining static in the body powder applications. It appears that business in the body powder segment is merely shifting around, particularly amongst the packagers.
- There are no new applications for talc, except some work in soap bars. One soap bar company, P&G, appears ready to move to customer trials and market testing.
- Surface treated talcs hold some promise, but more application research by the talc suppliers is needed to demonstrate the merits.

Pricing

- Pricing is an issue to the large volume consumers, but not an issue with the smaller higher value segments where quality, technical service and product performance are the key requirements expected of a supplier.

Health Concerns

- Some companies label their products "Talc Free", but this is more for advertising and sales promotion than to address health concerns.
- The general public is not aware of any health issues regarding talc.

Competition

- Most of the decline in talc usage has occurred during the past 5 years and has bottomed out.
- There are no serious replacement threats to talc. "Wheat", "Oat Flour" and "Corn Starch" are not direct threats to talc since they were introduced under the "natural" and "organic" banners. Although they have replaced some talc, they have proved to be less than ideal and are now more often used in blends with talc.

- Not many customers expressed a preference for a talc supplier, but those that did mentioned Luzenac.

Responsiveness to Survey

Several companies would not respond unless the survey sponsor was revealed – this was the over-riding concern of those that did not respond to the surveys. In addition, large body powder users were reluctant to respond to this survey because of health liability concerns and, to a lesser extent, because their companies have a policy against revealing confidential information.

At this point, Dodwell has contacted 96 companies and achieved a level of response slightly above 35% - I think this is better than expected.

- Twenty-one companies were called twice with no response and appear to use their voice mail as a screening tool. They include Coty, Kolmar Labs, Maybelline, Revlon (NJ), Colgate Palmolive and Amway.
- Eleven companies generally refused to participate in the survey. This group included J&J, MK Packaging, Thornton, Lancome/Cosmair, Lander, Estee Lauder and Revlon (NC).

Obviously, we are missing an input from several of the major players. To get their input we would have to either reveal the survey sponsor and/or raise their level of interest to respond. Their level of interest can be raised by appealing to their self-interest – "if I don't respond to this survey it may affect my supply of talc". In either case, a personal visit may be required. As I mentioned during my update at the last Management Meeting, revealing the sponsor or raising their level of interest is a double-edged sword – it either brings forth the desired response out of self-interest, or it generates a concern over the supplier's viability and loyalty to the market. It could cause them to consider other talcs or talc alternatives. At this point, I would recommend that Dodwell make no further extraordinary efforts to pursue those who are not responding. This can be a topic of discussion when Dodwell presents his findings at the October 5th meeting in Denver.

Exhibit 130



August 3, 1992

CONFIDENTIAL

SUBJECT: TALC FRANCHISE

TO: C. D. SIMONDS

Consumer confidence in talc has been slowly eroding, but among health care professionals, trust in its safety and benefits is poor. And, for the first time in over a decade, the FDA is now requiring reassurance. We have enjoined "risky" research with talc in the past - inhalation toxicity, translocation from the lungs, and genital migration studies. The time is ripe for some good news to definitively quieten theorizing critics.

My summary recommendations are as follows to re-establish our leadership in the talc category and rebuild its franchise:

1. Control any potential for inhalation by adding a small amount of lanolin oil to trap the respirables. This will also add a point of difference and improve both skin feel and benefits.
2. As rapidly as possible, complete the autopsy study of the mineral particle distribution in the organs of men versus women.

We should discuss this as soon as possible.

ADDENDUM

This morning I received your note attached to the new Cramer study. Our discussion earlier touched on this.

In summary:

- 1) A CTFA Task Force will fund a critical review of this paper, plus all other similar epidemiological studies to defuse the potential of anyone publishing a meta-analysis of all of them. You approved an expenditure for this effort.
- 2) The same CTFA Task Force will seek an evaluation of the NTP Inhalation Study which showed cancer in rodents. This refutation is critical to prevent the study results appearing on MSDS forms. You also approved our financial contribution to this effort.
- 3) At the first meeting of the Task Force, it was clear that "industry" agrees that a refutation of the ovarian cancer hypothesis based solely on discrediting existing publications, is only a "finger-in-the-dyke". I believe that they would be supportive of completing the autopsy study discussed above because it is the only way to finally put this issue to rest.

B. Semple

/cls

Johnson & Johnson

Office Of
GENERAL COUNSEL

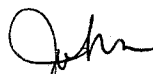
NEW BRUNSWICK, N.J.

December 5, 1994

SUBJECT: RITTER V. CYPRUS (WINDSOR MINERALS)

William Ashton ✓
Donald Jones

Redacted: Attorney-Client Privilege and Work Product



John C. O'Shaughnessy

JCO:jcm

Enc.

cc: R. Miller

Exhibit 131

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3
4 -----x
5 IN RE JOHNSON & JOHNSON) MDL No.
6 TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
7 MARKETING SALES PRACTICES,)
8 AND PRODUCTS LIABILITY)
9 LITIGATION)
10)
11 THIS DOCUMENT RELATES TO)
12 ALL CASES)
13 -----x

14
15 VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT
16 PERSONAL CARE PRODUCTS COUNCIL,
17 by and through its Designated Representative,

18 MARK POLLAK
19
20 WASHINGTON, D.C.

21 WEDNESDAY, AUGUST 29, 2018

22 9:30 A.M.

23
24 Reported by: Leslie A. Todd

1 Deposition of MARK POLLAK, held at the offices
2 of:

3

4

5 SEYFARTH SHAW LLP

6 975 F Street, N.W.

7 Washington, DC 20004

8

9

10

11

12 Pursuant to notice, before Leslie Anne Todd, Court
13 Reporter and Notary Public in and for the District of
14 Columbia, who officiated in administering the oath to
15 the witness.

16

17

18

19

20

21

22

23

24

A P P E A R A N C E S

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17 ALSO PRESENT:

18 EMILY H. MANOSO, Staff Counsel, PCPC

19 THOMAS F. MYERS, Staff Counsel, PCPC

20

21 DANIEL HOLMSTOCK (Videographer)

22 JONATHAN VADERS (Technical Support)

23 ZACH HONE (Technical Support)

24

1	C O N T E N T S		
2	EXAMINATION OF MARK POLLAK		PAGE
3	By Mr. Golomb		8
4			
5			
6			
7	E X H I B I T S		
8	(Attached to transcript)		
9	POLLAK DEPOSITION EXHIBITS		PAGE
10	No. 1	The Plaintiffs' Steering Committee's	
11		Second Amended Notice of the	
12		30(b)(6) Deposition of Defendant	
13		Personal Care Products Council	30
14	No. 2	PCPC Organizational Chart	33
15	No. 3	Document with title "Talc IP -	
16		Revenue Received"	61
17	No. 4	Document entitled "Payments to	
18		Entities Identified in Plaintiffs'	
19		Notice of Deposition"	112
20	No. 5	CTFA Mission Statement, Bates	
21		PCPC0052417	127
22	No. 11	Bates IMERYS 118791	93
23	No. 12	Bates IMERYS 118792	132
24			

1 P R O C E E D I N G S

2 -----

3 THE VIDEOGRAPHER: We are now on the
4 record. My name is Daniel Holmstock. I am the
5 videographer for Golkow Litigation Services.
6 Today's date is August 29th, 2018, and the time is
7 9:30 a.m.

8 This video deposition is being held in
9 the law offices of Seyfarth Shaw, LLP, at 975
10 F Street, Northwest, in Washington, D.C., in the
11 matter of In Re: Johnson & Johnson Talc-Based
12 Powder Products Marketing, Sales Practices, and
13 Products Liability Litigation. It is pending
14 before the United States District Court for the
15 District of New Jersey, MDL No. 16-2738.

16 The deponent today is Mr. Mark Pollak.

17 Counsel will be noted on the
18 stenographic record. The court reporter is
19 Leslie A. Todd, who will now administer the oath.

20 MARK POLLAK,

21 and having been first duly sworn,

22 was examined and testified as follows:

23 EXAMINATION BY COUNSEL FOR PLAINTIFFS

24 BY MR. GOLOMB:

1 Q Good morning, Mr. Pollak. My name is
2 Richard Golomb. We met several years ago when I
3 took your deposition in -- in another one of these
4 cases.

5 Do you recall that?

6 A Yes, I recall.

7 Q And if you could keep your --

8 A Yeah.

9 Q -- voice up so everybody --

10 A Yes, I recall.

11 Q -- in the room can hear you.

12 And in preparation for your deposition
13 here today, did you have a chance to read your
14 deposition transcript from that prior deposition?

15 A Yes, I did.

16 Q All right. Let me just mention a couple
17 of things. As you -- I assume that you have seen
18 the notice of deposition which requires your
19 attendance here today.

20 A Yes.

21 Q All right. And we'll -- we'll go
22 through that in a little bit more detail.

23 As you may know, the -- this deposition,
24 unlike the prior deposition, is limited to some

1 topics that we have agreed to cover with you
2 while other topics will be covered with Dr. Loretz
3 and perhaps some other people from PCPC.

4 Do you understand?

5 A Yes.

6 Q All right. And your role in this
7 deposition is a little bit different than the
8 deposition previously. Do you understand that?

9 A Yes.

10 Q So that you understand that your
11 deposition -- and you certainly don't need to know
12 the rule, but it's under rule -- federal
13 Rule 30(b)(6). Have you heard that term before?

14 A I don't recall.

15 Q Okay. But you do understand that the --
16 the topics that are in the notice are the topics
17 that I'm going to be questioning you here today.

18 A Yes.

19 Q All right. And those topics have been
20 limited as a result of an order of the Special
21 Master who's been appointed in this case. Do you
22 understand that?

23 A Yes.

24 Q All right. And so you understand that

1 it may be later on in this litigation that you may
2 be required to give yet another deposition. I
3 know you're looking forward to that, but you may
4 have to.

5 Do you understand that?

6 A Okay. Yes.

7 Q All right. Let -- let me also ask you
8 about -- you signed a verification to some answers
9 to interrogatories recently. Do you recall that?

10 A Yes, on Monday.

11 Q All right. And let me just -- we're
12 going to go through some of these answers in a
13 little bit more detail later. But let me just
14 show you page 31. There's a verification dated
15 August 27, 2018, and it has your signature on it.

16 Is that your signature?

17 A Yes, it is.

18 Q And did you in fact sign that on
19 August 27th?

20 A Yes, I did.

21 Q And when did you first see the
22 questions, the interrogatories?

23 A I may have just seen them on that
24 Monday. Some of them I may have seen previously,

1 but I can't -- I can't be sure.

2 MR. GOLOMB: Okay. I just want to just
3 say for the record that we received the answers to
4 these interrogatories -- interrogatories on
5 August 27th, 2018, at 4:45 p.m. There was an
6 agreement of counsel that these would be supplied
7 a week in advance of this deposition. Obviously
8 they weren't. So we -- we may -- after we look at
9 the interrogatory answers in more detail and
10 compare them to some records, we may be required
11 to come back and take another day of deposition on
12 this 30(b)(6) notice.

13 You don't need to respond to that. I
14 just wanted to let you know that that's -- that's
15 a possibility.

16 BY MR. GOLOMB:

17 Q When did you first find out that you
18 were going to be deposed?

19 A In this particular case?

20 Q Yeah.

21 A I would -- a few months ago, I would
22 think.

23 Q And have you been deposed in any other
24 cases other than the deposition I took of yours --

1 A No.

2 Q -- several years ago?

3 A No.

4 Q All right. And how did you learn that
5 you were going to be deposed?

6 A I think Tom Myers, our in-house counsel,
7 shared with me the fact and may have -- may have
8 forwarded the notice. I don't recall.

9 Q Okay. And since you learned that you
10 were going to be deposed again, I -- I assume that
11 you met with Mr. Myers in-house?

12 A Right. As well as Tom Locke.

13 Q Okay. Did you have any meetings with
14 Mr. Myers alone?

15 A I don't think so.

16 Q Did you speak to any other employees of
17 PCPC from the time that you -- you received notice
18 that you were going to be deposed until today?

19 A Not regarding the substance of the
20 deposition.

21 Q Were you aware that Linda Loretz was
22 deposed?

23 A Yes, I was.

24 Q How did you become aware that Linda

1 Loretz was deposed?

2 A Because I think I was copied on the
3 e-mail stream of trying to find mutually agreeable
4 dates for both of our depositions.

5 Q Okay. And before Ms. Loretz was
6 deposed, did you have any conversation with her
7 about her upcoming deposition?

8 A No, I did not.

9 Q And since she's been deposed, did you
10 have any conversation with her about her
11 deposition?

12 A No, I have not.

13 Q So you've never discussed with Linda
14 Loretz the content of either yours or her
15 depositions?

16 A Correct.

17 Q Did you read your deposition transcript?

18 A Yes, I did.

19 Q Did you read Linda Loretz's deposition
20 transcript?

21 A No.

22 Q So you didn't read the deposition
23 transcript that I -- of the deposition that I took
24 of Linda Loretz several years ago?

1 A That I can't recall.

2 Q You may have?

3 A But not -- but not in context of
4 preparing for this.

5 Q Okay. What -- if not for preparing for
6 this, why else would you read Linda --

7 A I don't --

8 Q Let me --

9 A I don't recall reading it.

10 Q Let me just give you one instruction.

11 You're doing fine, but if you will allow
12 me to finish my question, I will allow you to
13 finish your answer. That way --

14 A Sure.

15 Q -- neither one of us gets in trouble
16 with the court reporter. Okay? Okay?

17 A Yes.

18 Q And you also have to give a verbal
19 response.

20 A Yes.

21 Q All right. In what other context would
22 you read the deposition if not -- if not to either
23 prepare for this deposition or to have a
24 conversation with somebody?

1 A I can't think of any other context. I
2 know in preparation for this, I did -- I had read
3 the transcript of my original deposition whenever
4 the transcript became available last time, and I
5 think I -- I noted there were a few errors in the
6 transcription, and I did review that. And so in
7 preparation for today, I did read over that
8 deposition last week.

9 I did not read Linda's and I have no
10 recollection that I have, but I don't want to say
11 definitely that I didn't. It was
12 two-and-a-half -- more than two-and-a-half years
13 ago.

14 Q And when you say there were errors in
15 the transcription, what do you mean?

16 A There were -- they ask you to fill out a
17 form on different words the transcriber got wrong.

18 Q Okay.

19 A And that was filed with the deposition.

20 Q Was there any -- any errors in the
21 substance of what you said?

22 A I would say most of it was minor.

23 Q And is there anything that you read in
24 that deposition that you would now -- when you

1 read it you said, That wasn't right, or, Boy, I
2 wish I hadn't said that?

3 A No.

4 Q Anything like that?

5 A Nothing.

6 Q So whatever you said to -- whatever your
7 answer was to whatever my question was at that
8 earlier deposition, you stand by those answers?

9 A Yes.

10 Q When -- when did you learn that you were
11 going to be deposed?

12 A In this particular instance?

13 Q Yeah.

14 A I think in June or July.

15 Q And the meeting that you had -- well,
16 strike that.

17 You said you found out from Tom Myers.
18 Was that in person?

19 A It probably was on -- being copied on an
20 e-mail string.

21 Q And did you have a conversation with Tom
22 Myers?

23 A I -- I possibly did about this. I -- I
24 don't recall. I talk to him about lots of things,

1 so --

2 Q Okay. Well, have you ever had --
3 since -- since you received notice in June or July
4 of 2018 that you were going to be deposed here
5 today, have you ever had a one-on-one conversation
6 with Tom Myers about the fact that you were being
7 deposed here today?

8 A I probably did in terms of the
9 logistics.

10 Q Okay. Did you have any conversation
11 with Tom Myers about the substance?

12 A I don't think I did. Any conversation
13 would have been in the presence of Tom Locke.

14 Q And did you have any conversation
15 again -- I'm only restricting my questions to any
16 one-on-one meetings that you may have had with Tom
17 Myers.

18 Did you have any meeting, telephone
19 call, e-mail exchanges with Tom Myers about the --
20 about either, A, the substance of your deposition
21 here today or, B, how to prepare for the
22 deposition?

23 A Well, I think we did have a conversation
24 about how to prepare because we agreed that we

1 would meet with Tom Locke to review it.

2 Q Okay. And when was the first
3 communication that you had with Tom Locke after
4 you learned that you were going to be deposed here
5 today?

6 A Well, I met with him for the first time
7 in preparation for this last week.

8 Q Okay. So you had no conversation with
9 Tom Locke in June?

10 A I don't think so. I think it was all
11 through e-mails trying to find mutually agreeable
12 dates.

13 Q And the -- you had no communications
14 with Tom Locke other than the logistics of the
15 deposition in July?

16 A That's -- that's my recollection.

17 Q And -- and your testimony here today is
18 that the first time that you met with Tom Locke to
19 discuss your preparation for this deposition was
20 last week?

21 A That's correct.

22 Q Okay. And when last week was that?

23 A I'm not even sure which day. Possibly
24 Tuesday or Wednesday. I don't recall.

1 Q So either August 22nd or August --
2 either August 21st or 22nd?

3 A I think so, yeah.

4 Q And is that the first communication of
5 any kind you had with Tom Locke other than
6 logistics of when to meet since you received
7 notice of the -- received notice that you would be
8 deposed?

9 A I'm fairly certain.

10 Q And how long did your meeting last on
11 Monday or Tuesday of last week?

12 A I think it was three hours or less.

13 Q Okay. And without telling me about any
14 conversation that you may have had with Mr. Locke,
15 because that's a privileged communication, tell me
16 what you did during that three hours.

17 A We reviewed some potential questions and
18 some of the topics, what -- some of it was really
19 to refresh my memory on the whole process and what
20 to expect today and what I was expected to cover.

21 Q And was -- and is -- at that time did
22 you also review the deposition notice with -- that
23 included the topics?

24 A I actually don't recall.

1 Q Did you review any documents during that
2 three-hour period?

3 A I don't think so.

4 Q Did you review any documents to prepare
5 yourself before you had that meeting last week
6 with Tom Locke?

7 A I reviewed a few things in the office to
8 refresh my memory because there were topics that
9 were discussed in the last deposition, and I
10 wanted to be fresher on them.

11 Q Okay. What did -- what did you review?

12 A For example, the Cosmetic Ingredient
13 Review procedures that are online.

14 Q And specifically what is it that you
15 wanted to refresh your memory about as it relates
16 to the CIR?

17 A So there were some topics in the -- in
18 the last deposition that involved CIR, and I
19 wanted to be -- and I knew also some of the
20 procedures had changed in the last year, and I
21 wanted to be fresher on them.

22 Q What procedures changed in the last
23 year?

24 A There were a few updates and elimination

1 of redundancies, a couple of things that they
2 hadn't done in 20 or more years that they felt
3 were no longer...

4 Q Give me an example of what you're
5 talking about.

6 A I -- I can't even tell you off the top
7 of my head. They were really all pretty minor.

8 Q Okay.

9 A The CIR steering committee met in early
10 June to review the proposed changes to the
11 procedures and approve them then, and then they
12 were updated on our website.

13 Q And in June of 2018?

14 A Correct.

15 Q Okay. And do you know why those --
16 those procedures were changed?

17 A Because they -- a few of the things were
18 no longer necessary or practical and were
19 outdated. I think the procedures hadn't been
20 changed in ten or more years.

21 Q And were -- were those changes made at
22 all because of the talc litigation?

23 A Nothing related to talc.

24 Q Okay. So before you met with Tom Locke

1 last Monday or Tuesday, what other documents did
2 you review to help prepare yourself?

3 A He shared --

4 Q No, before you met.

5 A I don't think I reviewed anything before
6 I met with him.

7 Q Other than the CIR review?

8 A Right, and that was subsequent to our
9 meeting.

10 Q Okay. So then let's just be clear, then
11 you find out about the -- the deposition in June
12 or July. You have some conversation about
13 logistics with Mr. Myers. Don't have any
14 conversations with Tom Locke. You may have had an
15 exchange of e-mails to discuss logistics. You
16 finally agreed on a date to meet, which was early
17 to mid last week, and up until that time of that
18 meeting, you didn't review anything to assist you
19 in the preparation for today's deposition.

20 A Correct.

21 Q And then you -- you go to meet with
22 Mr. Locke, and you review some questions and some
23 potential answers to your deposition, but again,
24 on that particular day in the three-hour meeting,

1 you don't review any documents. Is that your
2 testimony?

3 A Yes.

4 Q Okay. And so who else was in the room
5 when you met for three hours with Mr. Locke?

6 A Tom Myers and Emily Manoso, who's our --
7 who also is a lawyer for the council.

8 Q Okay. And is that somebody who works --

9 A Right, she --

10 Q -- with Mr. Myers?

11 A Yes. She's in the room today.

12 Q Okay. Anybody else in the room?

13 A No.

14 Q Anybody from Mr. Locke's office in the
15 room?

16 A No.

17 Q And in -- at what time of day did this
18 meeting take place?

19 A In the morning.

20 Q And what time did it end?

21 A By 12:30.

22 Q And did you have any -- after you met
23 with Mr. Locke that day, did you discuss what
24 happened at that meeting with -- with Mr. Myers?

1 A No, I don't think I did.

2 Q Did you have any -- any homework
3 assignment, if you will, on what you should do
4 next to help yourself prepare for the deposition?

5 A No, and I don't remember the sequence of
6 events, whether I reviewed the transcript before
7 or after that meeting.

8 Q Okay. But you reviewed the transcript
9 of the prior deposition.

10 A Correct.

11 Q But you did not review the deposition of
12 Linda Loretz.

13 A Not -- not recently. I -- again, I'm
14 not sure whether I did two or more years ago.

15 Q Okay. And when you -- when you left
16 Mr. Locke after that three-hour meeting, had you
17 scheduled your next meeting?

18 A No, we hadn't.

19 Q Did you have a next meeting?

20 A Yes.

21 Q When was the next meeting?

22 A Yesterday.

23 Q Okay. And so -- and what time was that
24 meeting yesterday?

1 A It was also in the morning.

2 Q And how long did that meeting last?

3 A Two, two-and-a-half hours maximum.

4 Q Okay. And other than the possibility
5 that you may have read your -- your deposition
6 transcript from the prior deposition in that week
7 or so intervening period of time, did you review
8 any other documents?

9 A So we went over the document that --

10 Q Let me -- I'm sorry. Let me be clear
11 about my question.

12 You had told us that you read the --
13 your deposition transcript from the prior
14 deposition, but you weren't sure if it was before
15 or after that first meeting with Mr. Locke,
16 correct?

17 A Yes.

18 Q All right. And -- and so when you left
19 that meeting, you then scheduled another meeting
20 with Mr. Locke a week or so later, which would
21 have been two days ago, correct?

22 A We actually left it open whether we were
23 going to meet, but we decided we would.

24 Q Okay. But ultimately you decided to

1 meet on Monday.

2 A No. Yesterday was Tuesday.

3 Q Yesterday. And that was the first -- is
4 that the first conversation you had with Mr. Locke
5 since you left his office back on the 21st or
6 22nd?

7 A Yes.

8 Q And so my -- my -- going back to my
9 earlier question, from the time that you left
10 Mr. Locke's office on the 21st or 22nd until the
11 time you saw him yesterday, did you -- other than
12 the possibility that you may have read that prior
13 transcript, did you read any -- any -- did you
14 look at any documents?

15 A Well, again, because I signed the
16 interrogatories on Monday, I did read them.

17 Q Okay. I'm talking about before you met
18 with Mr. Locke on Monday.

19 A Well, I -- I reviewed the document and
20 signed it on Monday. I met with Mr. Locke on
21 Tuesday.

22 Q Okay. My question is, from the time
23 that you left Mr. Locke's office last week until
24 the time that you saw Mr. Locke this week, okay,

1 did you review any other documents?

2 A Not besides the interrogatories.

3 Q Okay. How did you receive the answers
4 to the -- the answers to interrogatories?

5 A Electronically, and then we printed them
6 out.

7 Q Okay. And when did you get those?

8 A On Monday.

9 Q And -- and you were in your office when
10 you received them?

11 A Yes.

12 Q And you reviewed them in your office?

13 A Yes.

14 Q And were the -- did you have any
15 conversation with Mr. Locke about those answers
16 before you received them electronically on Monday?

17 A No.

18 Q Okay. So just to be clear, that your --
19 in your office on Monday, at that point you had
20 never seen the -- the set of interrogatories. Am
21 I correct?

22 A This particular set, yes.

23 Q Right. And then you -- you get a set of
24 interrogatories that are both questions and

1 answers. The answers are already provided for
2 you. You're sitting in your office, you get them
3 electronically, you review them, and you sign the
4 verification.

5 A Yes.

6 Q And did you make any changes to the
7 answers?

8 A No.

9 Q Did you have any conversation with --
10 with Mr. Locke about those answers before you
11 signed the verification?

12 A No.

13 Q Did you have any conversation with
14 Mr. Myers before you signed the verification?

15 A I think I may have said to him, These
16 look fine.

17 Q Okay. So it's fair to say you didn't
18 have any input into the answers?

19 MR. LOCKE: Objection.

20 THE WITNESS: I -- these interrogatories
21 were similar in substance to many interrogatories
22 I've signed or reviewed in the past few years.

23 BY MR. GOLOMB:

24 Q Okay. In this set you didn't have any

1 input into the answers. Am I correct?

2 MR. LOCKE: Objection.

3 THE WITNESS: Correct.

4 BY MR. GOLOMB:

5 Q Okay. So the -- the -- did you only
6 have one meeting with Mr. Locke before -- this
7 week before today?

8 A I had one meeting last week, one meeting
9 yesterday.

10 Q I understand. So -- so this week
11 your -- other than today, this week your sole
12 meeting was yesterday?

13 A Yes.

14 Q All right. And when did that meeting
15 start, what time of day?

16 A 9:30.

17 Q And when did that meeting end?

18 A It ended I think by 12 o'clock.

19 Q Okay. And did you review any other
20 documents during that three-hour period of time?

21 A He may --

22 MR. LOCKE: It's just a "yes" or "no."

23 THE WITNESS: Yes.

24 BY MR. GOLOMB:

1 Q What did you review?

2 MR. LOCKE: Well, I'm not going to --
3 our selection of documents that I might have
4 showed the witness, that reflects our work
5 product. So he's not going to answer that
6 question. If you show him a document, you can ask
7 him if he reviewed it.

8 BY MR. GOLOMB:

9 Q Approximately how many documents did you
10 review?

11 A Two or three.

12 Q Well, let's -- let's go to the -- to the
13 notice for a second.

14 Mr. Pollak, for the record, we're going
15 to mark this as Pollak No. 1, and you can see
16 there's a red flag, and we will go right for
17 page 12, where the red flag is.

18 (Pollak Exhibit No. 1 was marked
19 for identification.)

20 BY MR. GOLOMB:

21 Q And you can see what I've done is I've
22 highlighted specifically the -- the topics that
23 you're noticed here today to answer. Okay?

24 A Yes.

1 Q And so let's start with under
2 subsection 3, "Issues relating to influence and
3 bias." Do you see that?

4 A Yes.

5 Q And under 3.1, PCPC, so you are here
6 today to answer my questions concerning the
7 purpose, function, responsibilities and missions
8 of PCPC. And you're also here to talk about
9 PCPC's structure, membership, dues system,
10 assessments, budgeting committees, and funding,
11 including entities funded in whole or in part by
12 PCPC, and financial contributions made to PCPC.

13 Do you feel you're prepared to answer
14 those questions today?

15 A Yes.

16 Q If we go to the next page, page 13 of
17 that document, under number 2: You are also here
18 to answer questions about PCPC's relationship with
19 J&J and J&JCI, including formal and informal J&J
20 and J&JCI representatives and J&JCI or J&J
21 financial contributions to PCPC, including to
22 committees and/or subcommittees.

23 You feel you're prepared to answer
24 questions about that today?

1 A Yes.

2 Q Under subsection 3, under Imerys, you're
3 here to answer questions about PCPC's relationship
4 with Imerys, including formal and informal
5 representatives, and financial contributions to
6 the PCPC, including to committees and/or
7 subcommittees.

8 Do you feel like you're prepared to
9 answer questions about that today?

10 A Yes.

11 Q If you go to page 15 of the document.
12 It's entitled "National Cancer
13 Institute" under subsection 7. Do you see that?

14 A Yes.

15 Q Under subsection (b), you're here to
16 talk about the knowledge concerning financial
17 support to NCI and the persons who make
18 recommendations to NCI within the -- within and
19 outside the organization.

20 Do you feel like you're prepared to
21 answer those questions?

22 A Yes.

23 Q And under subsection 10, on page 16 --
24 you'll see on page 15 it says "The cosmetic

1 industry review," and subsection (d) is: "PCPC's
2 relationship with CIR, including funding,
3 staffing, membership, formal and informal
4 meetings, committees and/or subcommittees."

5 Do you feel like you're prepared to
6 answer questions on those topics today?

7 A Yes.

8 Q Okay.

9 MR. GOLOMB: Let's mark this as No. 2.
10 There's some extra copies there. This will be
11 marked as Plaintiffs' Exhibit 2.

12 (Pollak Exhibit No. 2 was marked
13 for identification.)

14 BY MR. GOLOMB:

15 Q While Mr. Locke is circulating that,
16 Mr. Pollak, you understand, do you not, that your
17 answers here today as a 30(b)(6) deponent are
18 binding on PCPC?

19 A Yes.

20 Q So you're not just here in your own
21 personal capacity. You understand that, correct?

22 A I'm a corporate representative.

23 MR. GOLOMB: Now, I'm going to show him
24 the document.

1 MR. LOCKE: Oh, okay. Do you want to
2 mark this?

3 MR. GOLOMB: Yeah, this one is marked.
4 Why don't you give me that one back. Thanks.

5 BY MR. GOLOMB:

6 Q Now, you're familiar with this document,
7 are you not?

8 A Yes.

9 Q This is an organizational chart. In
10 fact, it's an organizational chart that you
11 supplied to me right before the last deposition.
12 Do you recall that?

13 A Yes.

14 Q Is this an organizational chart that
15 you -- that you yourself prepared, or is this
16 something that was previously prepared that you
17 brought with you at that prior deposition?

18 A I actually don't recall.

19 Q Okay. Is this something -- whether or
20 not it was specifically for that deposition or
21 not, is this something that you prepared?

22 A I would have reviewed it. I don't
23 recall that I would have prepared it at the time.

24 Q Okay. What -- what's your title?

1 A So I'm on this as senior executive
2 vice president. At the time it was strategic
3 initiatives membership and marketing. It's now
4 changed to senior executive vice president, chief
5 operating officer.

6 Q Okay. And this was previously marked on
7 February 18, 2016, the date of our prior
8 deposition, correct?

9 A Well, here it's marked today's date. So
10 I -- I wouldn't know.

11 Q Okay. Well, let me show you the prior
12 copy where -- you see?

13 A Okay. Yes.

14 Q Is that consistent with your
15 recollection of when the prior deposition was?

16 A Yes.

17 Q And you've got a change of title since
18 then. Do you have -- is your job description
19 different?

20 A It's fairly similar.

21 Q How would you -- what's your job
22 description?

23 A I am the -- the chief operating officer
24 responsible for working with all the senior staff

1 on providing -- in coordinating our policies and
2 our approach so we can best represent the industry
3 and be responsive to our board of directors.

4 Q And is it -- you're not a scientist,
5 correct?

6 A Correct.

7 Q And is it fair to say that your -- your
8 job is more kind of internal administrative than,
9 you know, scientific or public relations or
10 political?

11 A Yes, but it involves all those
12 components because I have to work with all the
13 EVPs on -- on the major issues.

14 Q And let's just go through this, if we
15 could, because I think what this does is it gives
16 us the -- kind of the different departments within
17 the organization, correct?

18 A Yes.

19 Q How many current employees are there at
20 PCPC?

21 A I think the count is around 56.

22 Q All right. And first of all, looking at
23 page 1 of Exhibit 2, is Lezlee Westine -- is it
24 Westin (phonetic)?

1 A Westine.

2 Q Westine. Is she still the president and
3 CEO?

4 A Yes, she is.

5 Q And just as we quickly go through the
6 employees on the bottom of the page, are they all
7 the same or have there been changes?

8 A So there are two changes. The first one
9 is Elizabeth Anderson is no longer there. Tom
10 Myers is EVP, legal and general counsel.

11 Q What's the other change?

12 A And the other one is the EVP Science,
13 Beth Lange, is no longer there and her replacement
14 is Alexandra Kowcz.

15 Q Alexandra?

16 A Right.

17 Q Couch?

18 A K-O-W-C-Z.

19 Q And why did Elizabeth Anderson leave?

20 A She retired.

21 Q And why did Beth Lange leave?

22 A She relocated with her husband to Utah.

23 Q If we go to the next page of the
24 exhibit. Looking at the legal department, any

1 changes?

2 A Right. So Farah Ahmed has also left,
3 and Emily Manoso has taken her slot.

4 Q And why did Farah Ahmed leave?

5 A She left for another job.

6 Q And do you know where that is?

7 A Yes. The organization changed to -- its
8 name is Fragrance Creators. It's a trade
9 association representing fragrance ingredient
10 manufacturers.

11 Q The next department is Government
12 Affairs department. First of all, tell me
13 generally what Government Affairs department does.

14 A So that would be the closest to lobbying
15 federal and state relations, representing the
16 industry before different state regulatory bodies
17 and federal.

18 Q Okay. Any -- any changes in that
19 department since the last deposition?

20 A No.

21 Q On the next page, Public Affairs and
22 Communications.

23 A So there -- Lisa Powers is still there.
24 The other two people have left. Jewel Jones has

1 taken Hayley McConnell's position, and Jamie Kirk
2 has taken Lauren Brady's position.

3 Q What does Public Affairs and
4 Communications department do?

5 A So they work with our members to present
6 the industry's viewpoint to the media, monitor how
7 the industry is being covered by the media, and
8 work on external communications materials for the
9 organization.

10 Q And when you say "external materials,"
11 what do you mean?

12 A For example, our annual report. We're
13 in the process of redoing our website, and they're
14 working on the website redesign.

15 Q And why did Hayley McConnell leave?

16 A I think she decided to stay home with
17 her children.

18 Q And why did Lauren Brady leave?

19 A I think she got a better job.

20 Q Where is she?

21 A I don't recall.

22 Q What does Global Strategies department
23 do?

24 A So that's our international department.

1 We monitor and advise our members on a lot of
2 international cosmetic regulations, and they're
3 the department that handles that. It also works
4 to get uniform regulation worldwide of cosmetics
5 and represent the industry's viewpoint on trade
6 negotiations.

7 Q And when you say "works to get uniform
8 regulation worldwide of cosmetics," what do you
9 mean?

10 A So that the -- for example, the
11 regulations in the European Union would be
12 compatible with FDA regulation so that companies
13 who sell their products in numerous markets do not
14 have to comply with inconsistent regulations.

15 Q And have any of the employees within the
16 Global Strategies department changed?

17 A Yes. Tonya Kemp is no longer there, and
18 Natalie Obermann, I think is her last name, has
19 replaced her.

20 Q Why did Tonya Kemp leave?

21 A She left for a better job.

22 Q Where did she go?

23 A She's working for Amway.

24 Q And Finance and Administration, what --

1 what do they do?

2 A So that is the accounting, human
3 resources, information technology, things like
4 that.

5 Q Is that where -- did you come up -- in
6 the company come up through finance and
7 administration?

8 A Not really. It was a separate
9 department from that.

10 Q What department did you come up through?

11 A It's no longer a separate department.
12 At the time it was member relations.

13 Q Okay. Any changes in Finance and
14 Administration?

15 A Yes. So we no longer have a
16 vice president of finance, and -- he retired. And
17 we have -- the person who took his place, Al Fox,
18 I actually don't know -- don't recall his new
19 title, but he is higher than an accounting manager
20 but he's not a vice president.

21 Q Okay. Any other changes for Finance and
22 Administration?

23 A So we no longer have a receptionist who
24 is an employee of the council. We have somebody

1 from a temp agency. And there are -- there's a
2 new staff accountant.

3 Q Who is that?

4 A Dan, and I can't remember his last name.

5 Q Now, on this -- on this document it says
6 "Accounting manager, vacant," and you described Al
7 Fox as the accounting manager. Is that --

8 A No, he's higher than an accounting
9 manager. So what would be here, the VP finance
10 accounting manager and staff accountant, we
11 currently are handling with two full-time
12 employees, and then it's supplemented by a --
13 either a part-time or a temporary accounting
14 employee, who is just there two or two-and-a-half
15 days a week.

16 Q And then on -- you also have the Science
17 department. What does the Science department do?

18 A So the Science department works with our
19 member companies on -- to monitor the -- the
20 latest information on science data, ingredient
21 safety relating to our products. There are a
22 number of committees. We have international
23 nomenclature that's handled through a committee in
24 the Science department that forms the platform for

1 the database services that we have for our
2 members, and we do a variety of science and
3 technical publications that are based on this
4 nomenclature and other...

5 Q Give me an example of a standing
6 committee.

7 A So the pharmacology and toxicology
8 committee.

9 Q Now, there are a number of interested
10 party task forces, correct?

11 A Yes.

12 Q And as an example, we know that there is
13 a Talc Interested Party Task Force, correct?

14 A Yes.

15 Q And is -- first of all, is the Talc
16 Interested Party Task Force considered a standing
17 committee?

18 A No.

19 Q What's -- what is it considered?

20 A It's a -- it's a task force, so a task
21 force would be of limited interest to the broad
22 membership.

23 Q Okay.

24 A A standing committee would be a concern

1 or a topic that's much more common among them.

2 Q And do task forces kind of come and go
3 depending on the issue of the day as it relates to
4 that particular task force?

5 A Some of them do. Some of them are
6 around for a long time.

7 Q Okay. How would you describe -- in that
8 context, how would you describe the Talc
9 Interested Party Task Force?

10 A It's obviously been in existence for
11 quite a while.

12 Q And when was it started?

13 MR. LOCKE: Well, objection. It's
14 beyond the scope.

15 You can answer if you can.

16 THE WITNESS: I don't recall. I think
17 probably in the 1980s.

18 BY MR. GOLOMB:

19 Q And why was it started?

20 MR. LOCKE: Objection. Beyond the
21 scope.

22 THE WITNESS: I don't know. I mean,
23 I -- I think it started before I came there.

24 BY MR. GOLOMB:

1 Q When -- when did you come to the
2 company?

3 A In 1983.

4 Q Okay. And so the Talc Interested Party
5 Task Force was started obviously before 1983.

6 A I think so.

7 Q Okay. Are you aware one way or the
8 other as to whether or not the Talc Interested
9 Party Task Force was started in response to Dr.
10 Dan Cramer's study back in 1982?

11 MR. LOCKE: Objection. Beyond the
12 scope.

13 THE WITNESS: I don't know who Dr. Dan
14 Cramer is.

15 BY MR. GOLOMB:

16 Q Okay. So in terms of the standing
17 committees, approximately how many of them are
18 there?

19 A Maybe 25. I think we provided a -- the
20 committee roster and description.

21 Q And in terms of the interested party
22 task forces, approximately how many of them are
23 there?

24 A There could be 10 to 20. Some of them

1 are not particularly active. They're more contact
2 lists.

3 Q Give me an example of a -- of the
4 currently active task force other than talc.

5 A Sunscreen.

6 Q All right. Looking at the Science
7 committee on this document, any changes?

8 A We already noted Beth Lange. John
9 Krowka has retired. And Carmela Wingfield has
10 left.

11 Q Did somebody take Beth Lange's place?

12 A Right. Alex Kowcz. Couch (phonetic).
13 I always get this messed up.

14 Q Did somebody take John Krowka's place?

15 A Yes. Dan, and I don't remember his last
16 name.

17 Q Anybody take Carmela Wingfield's place?

18 A No.

19 Q If we go to the next page, Strategic
20 Initiatives, what is that?

21 A So that was from my old title, and then
22 they had Marketing and Member Services as a
23 separate department.

24 Q What is Strategic Initiatives?

1 A So, again, it was, you know, working on
2 the major program initiatives for the association
3 and working with the board of directors to
4 implement policies and --

5 Q When you say "program initiatives," what
6 do you mean?

7 A You know, different -- whether it's in
8 the sustainability area or animal testing,
9 alternatives, things like that.

10 Q Marketing and Member Services, any
11 changes?

12 A So Jennifer Harwell has left for another
13 job. Catherine McDonald was promoted and is
14 handling membership as well as meetings. Huyen
15 Tran has retired. And Ashley Hilton has left, and
16 Carmela Douglas, who was the former receptionist,
17 has taken over her slot.

18 Q So Carmela --

19 A -- Douglas, who is on the organ- -- this
20 organization chart as the receptionist.

21 Q So are you --

22 A Carmen.

23 Q On this chart that you've provided to us
24 in February of 2016, it identifies you as the

1 senior EVP membership and marketing.

2 Do you still maintain that title?

3 A No. It has -- it has both titles, and
4 I -- I don't know why.

5 Q Do you still maintain that job function?

6 A They were -- I sort of absorbed that job
7 function into my current job.

8 Q Okay. And did anybody take over
9 Catherine McDonald's position?

10 A No, she's still there. She got promoted
11 and has taken over Jennifer Harwell's position.

12 Q Okay. Anybody take over Jennifer
13 Harwell's position?

14 A No. That's vacant.

15 Q Anybody take over as operations manager?

16 A We have a part-time employee who is
17 handling what Mr. Huyen did.

18 Q And what's that person's name?

19 A Mr. Xu.

20 Q Okay. If we look at the next page, it's
21 got the organizational chart for the Personal Care
22 Products Council Foundation. What is that?

23 A So it is a separate entity that runs our
24 Look Good Feel Better program for women undergoing

1 cancer treatment.

2 Q And what is the Look Good Feel Better
3 program?

4 A We provide makeover sessions for women
5 undergoing cancer treatment to help them deal with
6 the side effects of chemotherapy and radiation.

7 Q And what is the approximate revenue base
8 for that?

9 A So that is entirely based on
10 contributions and proceeds from fundraising
11 activities and cause marketing programs.

12 Q And approximately how much revenue per
13 year is in that program?

14 A I think it's close to \$2 million.

15 Q Where does the money come from?

16 A I just said contributions, cause
17 marketing agreements.

18 Q Contributions from -- from who?

19 A From women who've undergone the program,
20 other people in the cancer community, but it's
21 more the proceeds from fundraising events and
22 cause marketing programs.

23 Q And these seven people who are
24 identified as employees of the Personal Care

1 Products Council Foundation, are they also
2 considered employees of the Personal Care Products
3 Council?

4 A Yes. So they're part of our personnel
5 system and salary and benefits, but the -- the
6 money to pay them and their benefits and a
7 percentage of the overhead comes from the
8 foundation.

9 Q And these seven people, have that --
10 have there been any changes since?

11 A Yes. This Alexandra is no longer there,
12 and she's been replaced by Shayma, and I can't
13 remember her last name.

14 Q Okay. In addition to the individual
15 contributions that you were just talking about, do
16 you get any contributions into the foundation from
17 any of the PCPC members?

18 A So the -- the member companies, yes, do
19 provide a lot of the funding indirectly because of
20 this major fundraising event called the DreamBall
21 that's held in September in New York. Until this
22 year, we had done it in partnership with the
23 American Cancer Society. So the companies buy
24 tables, and most of these -- many of them are

1 member companies, and then there are other
2 fundraising activities associated with the event.

3 Q Okay. Is it fair to say that the --
4 that the DreamBall fundraiser is your number one
5 fundraiser for the foundation?

6 A Yes.

7 Q And does -- is J&J -- J&J, are they a
8 sponsor of the DreamBall?

9 A They're certainly a participant, yes.

10 Q And do you know -- can you tell me
11 approximately how much on an annual basis they
12 contribute to the foundation?

13 A I can't tell you exactly. They may buy
14 a table, and it may be something in the -- it's
15 twenty, \$25,000.

16 Q And does -- Imerys is a member of the
17 PCPC, correct?

18 A They have been. I actually didn't check
19 whether they were a member this year.

20 Q All right. And have they been a
21 contributor to the DreamBall?

22 A Not that I know of.

23 Q Have they been a contributor in some
24 other way to the foundation?

1 A Not that I know of.

2 Q The -- the employees of the foundation,
3 do they -- whether they get paid on a weekly or
4 biweekly basis, do they get paid by PCPC?

5 A Right. So they're part -- they're part
6 of our ADP payroll system and the same benefit
7 plans, but the money is allocated to come from
8 their separated funds from the donations.

9 Q Okay. But their check comes from PCPC.

10 A Yes.

11 Q And their office is in the PCPC space?

12 A Yes.

13 Q And whether it's you or somebody else,
14 somebody -- some executive in administration for
15 PCPC oversees kind of the administrative things
16 for the foundation.

17 A Yes.

18 Q Okay. Next on your list is the Cosmetic
19 Ingredient Review. Have there been any changes
20 here?

21 A So the executive director, Lillian Gill,
22 retired. Bart Heldreth, who's listed as chemist,
23 was promoted to executive director. Monice is --
24 I think her title is deputy, or she's the

1 equivalent. I don't know her exact title. Ivan
2 Boyer, senior toxicologist, has left. Lillian
3 Becker is no longer there, and so then three new
4 employees have been hired to fill these slots.

5 Q Who hires these new employees?

6 A The director of -- the executive
7 director of CIR.

8 Q And is there input from PCPC?

9 A There's some input on salary range. I
10 may have met one or two of them.

11 Q Are you the -- are you the final decider
12 on how much an employee of Cosmetic Ingredient
13 Review gets paid?

14 A Me and others.

15 Q Who are the others?

16 A Kris Bogenrief, who is our CF chief
17 financial officer, would have input on that also.
18 We have salary ranges and they have a budget
19 and --

20 Q Okay. But -- so just to be clear, when
21 you're talking about you, Mark Pollak, and others
22 that have the final say on the cosmetic -- the
23 salaries on the Cosmetic Ingredient Review, the
24 others are employees of the PCPC, correct?

1 A Correct.

2 Q And the checks that the people from
3 Cosmetic Ingredient Review receive are PCPC
4 checks?

5 A Yes.

6 Q And they -- do you use a --

7 A Payroll service?

8 Q -- payroll service?

9 A Yes.

10 Q And do they get paid through the same
11 payroll service?

12 A Yes.

13 Q And is there somebody at PCPC that is
14 responsible for -- first, let me strike that.

15 Do you get paid on a weekly basis,
16 biweekly basis, monthly --

17 A Biweekly.

18 Q Okay. And is there somebody at PCPC
19 that is responsible for calling in the numbers to
20 the payroll service?

21 A Right, the accounting department.

22 Q And that would be the accounting
23 department of PCPC?

24 A Correct. They don't have any admin- --

1 CIR would not have that internal function.

2 Q Right. So the -- the employees of PCPC
3 are calling in the payrolls of the employees of
4 PCPC council, PCPC Foundation, and CIR, correct?

5 A Yes.

6 Q And you and other employees of PCPC are
7 the ones who have the final say-so on how much an
8 employee of Cosmetic Ingredient Review gets paid?

9 A Yes.

10 Q And when you gave me the numbers
11 earlier, I think -- correct me if I'm wrong, I
12 think you said there was something like 53 or 56
13 employees. Were you counting PCPC, foundation and
14 CIR?

15 A Yes.

16 Q Okay. So how many specific employees
17 are there on the PCPC council?

18 A I think it's approximately 40.

19 Q And on the foundation?

20 A So the foundation has six or seven, and
21 CIR has seven or eight.

22 Q All right. On the Cosmetic Ingredient
23 Review, who took over as senior toxicologist?

24 A He has an Asian name that I can't

1 pronounce. Sorry.

2 Q Who took over as chemist for Bart
3 Heldreth?

4 A So that -- that slot, I think is Alison,
5 and again, I don't remember her last name.

6 Q Who took over as scientific analyst for
7 Monice?

8 A Well, we didn't fill that slot. She
9 just got a promotion. It would be the replacement
10 for Lillian Becker, and it's a woman, Priya, and I
11 don't -- don't recall her last name.

12 Q And everybody else remains the same?

13 A Yes.

14 Q Does PCPC do performance reviews of its
15 employees?

16 A Most -- most departments do.

17 Q Okay. Tell me how that -- generally how
18 it works.

19 A So it's an annual system. There's a
20 template that's provided by human resources that's
21 distributed I think in January or February, and
22 the supervisor prepares a write-up and meets with
23 the people that he or she supervises, and then a
24 copy is provided to human resources.

1 Q Okay. So let's take a look at the
2 Science department as an example, okay? And let's
3 just take the senior environmental scientist, Iain
4 Davis.

5 So the template of a -- of the review
6 would be provided to his supervisor?

7 A Correct, Alex. Yeah, the senior -- the
8 EVP for Science would be responsible. She
9 basically supervises the team. I think you'll
10 find lower down that some of the managers are
11 supervising people below them. She doesn't have
12 nine direct reports. She probably has four or
13 five.

14 Q Okay. But is -- is the EVP in each
15 department ultimately responsible for the
16 performance review of each employee in their
17 department?

18 A Yes.

19 Q Okay. And is that true of the PCPC
20 Foundation?

21 A Yes.

22 Q So Louanne Roark in this case would be
23 the -- be doing the performance reviews of the
24 other six people in the foundation?

1 A Yes.

2 Q And then once those performance reviews
3 are completed, they go where?

4 A To our personnel department, human
5 resources.

6 Q Okay. And would the same be true of
7 Cosmetic Ingredient Review, that is now --

8 A Yes.

9 Q -- Bart Heldreth would do the
10 performance reviews of everybody within the CIR,
11 and then they would go to human resources at PCPC.

12 A Right.

13 Q And what generally do you do with those
14 performance reviews?

15 A I think they go in the employee's file.

16 Q Okay. And so in terms of the process,
17 it's pretty much the same for the PCPC
18 employees --

19 A Right, they're subject to all --

20 Q Let me just finish the question.

21 It's pretty much the same for the PCPC
22 employees, the foundation employees and the CIR
23 employees?

24 A Yes.

1 Q All right. And the -- these people in
2 the foundation, they -- I think you had told us
3 previously that they have offices within the PCPC
4 offices, correct?

5 A Yes. We're all on the same floor.

6 Q Right. And the same is true of the CIR?

7 A Yes.

8 Q And so the foundation is completely
9 funded by PCPC.

10 A No.

11 MR. LOCKE: Objection.

12 BY MR. GOLOMB:

13 Q Other than the outside -- the outside
14 funding that we talked about before, the
15 fundraisers, the contributions from individuals.

16 A We don't fund them at all. All the
17 money of the -- we are reimbursed by the
18 foundation, you know, even for every square foot
19 of space they occupy.

20 Q Okay. And the --

21 A I think they're a (c)(3). We're a
22 (c)(6).

23 Q Okay. The CIR is completely funded by
24 the PCPC?

1 A Yes.

2 Q There's no reimbursement there?

3 A No.

4 Q There's no outside funding there?

5 A No.

6 Q So the -- the CIR employees get paid by

7 PCPC, correct?

8 A Yes.

9 Q Their office space is paid for by PCPC?

10 A Yes.

11 Q Their office supplies are paid for by

12 PCPC?

13 A Yes.

14 Q If they have -- if they have an office,

15 they're told where to sit by somebody at PCPC?

16 A I wouldn't go that far, but it would be

17 the director -- the executive director of CIR,

18 right.

19 Q Well, when a new employee comes in and

20 they're told, This is going to be your office,

21 it's the final --

22 A He would make --

23 -- the final decision of the PCPC.

24 A Indirectly.

1 Q What do you mean "indirectly"?

2 A The executive director would make that
3 kind of decision on the space allocation.

4 Q Okay. Do you -- are there -- are there
5 regular hours at the PCPC?

6 A There's a basic workday, but there is --
7 we are supportive of flexible schedules.

8 Q Okay. And is that -- the basic workday,
9 is that in a manual for -- some sort of procedures
10 manual?

11 A We have an employee handbook, and I
12 actually don't recall whether it says -- it
13 probably does say the basic workday is 9:00 to
14 5:00.

15 Q And the -- the employee handbooks covers
16 the employees of the Cosmetic Ingredient Review?

17 A Yes.

18 MR. GOLOMB: Let's mark this No. 3.

19 (Pollak Exhibit No. 3 was marked
20 for identification.)

21 BY MR. GOLOMB:

22 Q I'm going to show you a document which
23 is marked as Pollak No. 3.

24 You've seen that before, correct?

1 A I think I have.

2 Q In fact, I think, if my memory serves me
3 right, you told me at the last deposition that you
4 prepared this.

5 A No, I wouldn't have. The accounting
6 department would have prepared it. It's possible
7 I reviewed it, but I wouldn't have the capability
8 of preparing it.

9 Q Okay. Did they prepare it at your
10 request after I asked Dr. Loretz some questions
11 about it, and she was unable to answer it, and so
12 you took it upon yourself to have this prepared?
13 Does that sound familiar?

14 A I don't recall the sequence of events.

15 Q All right. In any event, this is a -- a
16 general ledger which shows the contributions
17 between 1992 and 2009 into the Talc Interested
18 Party Task Force, correct?

19 A Yes.

20 Q And there's -- the numbers total just
21 under \$440,000, correct?

22 A Yes.

23 Q More than half of which came from
24 Johnson & Johnson and Luzenac America, which we

1 know is now Imerys, correct?

2 A Yes.

3 Q By far the largest being Johnson &
4 Johnson, correct?

5 A Yes.

6 Q Now, I had asked you some questions
7 before about the interested party task forces
8 generally and how they kind of come and go. Some
9 come and go dependent on the issue of the day as
10 it relates to that subject, correct?

11 A Yes.

12 Q And so would it be fair to conclude from
13 this ledger that the Talc Interested Party Task
14 Force was active in 1992, '93, '94, and '97, 2000,
15 2001, 2005, 2008, and 2009?

16 A Yes. However, sometimes when there are
17 contributions made, it's just because there are
18 funds that are depleted in the account. It
19 doesn't mean there's a big activity at that
20 particular time, but...

21 Q Well, by far the largest activity on
22 this was in -- 1992 was one of the most active
23 years, correct?

24 A Yes.

1 Q And --

2 A For solicitation of funds.

3 Q Okay. And are you aware that 1992 was a
4 year that Dr. Cramer authored and reported his
5 second study on the relationship between talc and
6 ovarian cancer?

7 MR. LOCKE: Objection. Beyond the
8 scope.

9 THE WITNESS: No.

10 BY MR. GOLOMB:

11 Q So you don't know one way or the other
12 as to whether it's just a coincidence that the
13 second most active year was the year that
14 Dr. Cramer's study came out?

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 THE WITNESS: I -- I don't know.

18 BY MR. GOLOMB:

19 Q Okay. And you know you're aware -- you
20 know what the NTP is?

21 A Yes.

22 Q Okay. And is it just a coincidence that
23 the year in which more than half of the funds over
24 the last -- over the 17 years was in the year that

1 the NTP was evaluating whether or not to report
2 out talc as a carcinogen?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 THE WITNESS: Again, I wouldn't have any
6 independent knowledge.

7 BY MR. GOLOMB:

8 Q Okay. So you haven't spoken to anybody
9 or reviewed any documents to prepare for your
10 deposition here today which would show that the --
11 by far the largest expenditures from the Talc
12 Interested Party Task Force were to defend itself
13 in the NTP review?

14 MR. LOCKE: Objection to form and beyond
15 the scope.

16 THE WITNESS: No, I didn't.

17 BY MR. GOLOMB:

18 Q Okay. Do you know where the money that
19 was accumulated in 2000 went?

20 A I actually do not.

21 Q Do you know who Dr. Josh Muscat is?

22 A No.

23 Q Do you know who Dr. Huncharek is?

24 A No.

1 Q Do you know who the Weinberg Group is?

2 A Yes.

3 Q Who is the Weinberg Group?

4 A They're a consulting group in Washington
5 that I know we've worked with.

6 Q Okay. And do you know whether or not
7 the Weinberg Group was retained by the PCPC to
8 defend its members in the NTP review?

9 MR. LOCKE: Objection to form and beyond
10 the scope.

11 THE WITNESS: I know the Weinberg Group
12 was involved with helping with the presentation
13 for NTP.

14 BY MR. GOLOMB:

15 Q And do you know how much of the \$245,000
16 and the \$29,000 that was collected by the task
17 force in 2000 and 2001 went to the Weinberg Group?

18 A No, I don't.

19 Q Do you know, and correct me if -- I may
20 get the name wrong, but there's a crisis
21 management company called Nichols-Denzenhall.

22 A Dezenhall, yeah.

23 Q Okay. Do you know who they are?

24 A Yes.

1 Q Who are they?

2 A So they're a crisis management and
3 public relations firm in Washington.

4 Q What is a crisis management firm?

5 A So we had started working with them
6 earlier. They help organizations if there's a --
7 if there's a lot of media attention focus on a
8 particular safety issue, for example.

9 Q And had Dezenhall ever been hired by the
10 PCPC before 2000?

11 A Yes.

12 Q For what issues?

13 A There was a big issue in -- earlier in
14 the '90s about multiple chemical sensitivity
15 involving fragrances.

16 Q Anything related to talc?

17 A I know he made a proposal for doing some
18 work on talc, and I don't recall where that went
19 or how.

20 Q Okay. So do you know if or how much of
21 the money collected by the Talc Interested Party
22 Task Force went to the Dezenhall group as a -- for
23 crisis management fees in 2000 and 2001?

24 MR. LOCKE: Objection. Form, beyond the

1 scope.

2 THE WITNESS: And I don't know.

3 BY MR. GOLOMB:

4 Q And none of the documents that you
5 reviewed to prepare for your deposition here today
6 assisted you in that way?

7 A So, again, I -- if I recall,
8 Nichols-Dezenhall was involved perhaps with a
9 focus group. I know they had some involvement
10 with the issue and made a proposal, but I...

11 Q Okay. If you assume for the purpose of
12 my question that both the Weinberg Group and
13 Nichols-Dezenhall were both hired around the time
14 of -- in 2000 when the NTP was reviewing whether
15 or not to include talc as a carcinogen, I want you
16 to assume that to be true for the purposes of my
17 question.

18 So as you sit here today, you've never
19 read the Weinberg report as it relates to talc?

20 MR. LOCKE: Objection. Beyond the
21 scope.

22 THE WITNESS: I don't recall ever seeing
23 it.

24 BY MR. GOLOMB:

1 Q And you haven't reviewed the Dezenhall
2 report as it relates to talc?

3 MR. LOCKE: Objection. Beyond the
4 scope.

5 THE WITNESS: I don't even know if there
6 is a report.

7 BY MR. GOLOMB:

8 Q Okay. Is it -- if Dezenhall or Weinberg
9 had been hired to -- to do their work in -- with
10 respect to some other ingredient that may affect
11 some other member, in the scope and course of your
12 employment, is that something that you would see?

13 A Possibly at the time, but it's so long
14 ago, I can't recall what I did read and I didn't
15 read. I mean, we had previous relationships with
16 both organizations on -- on other matters.

17 Q Okay. So, as you sit here today, you
18 just don't recall one way or the other as to
19 whether or not you read those reports as they
20 relate to the association between talc and ovarian
21 cancer?

22 MR. LOCKE: Objection. Beyond --

23 BY MR. GOLOMB:

24 Q Is that correct?

1 MR. LOCKE: Beyond the scope.

2 THE WITNESS: I may -- I probably would
3 not have read a report that would be -- or a
4 submission to the NTP at that time.

5 BY MR. GOLOMB:

6 Q Would you -- would you -- as part of
7 your job, would you have known how much these
8 entities were paid?

9 A At the time I would have known it, but I
10 don't recall now this many years later what --
11 what was discussed.

12 Q Okay. What's the purpose of the PCPC?

13 A So we are the national trade association
14 that represents cosmetic, toiletry and fragrance
15 manufacturers and distributors in the U.S., and
16 providing them with technical reg- -- and
17 regulatory information to represent them on
18 government affairs, public affairs, and to work to
19 obtain international uniformity on cosmetic
20 regulation.

21 Q Now, does either you or somebody at the
22 PCPC have regular dealings with the FDA?

23 A Yes.

24 Q Now, just looking at your list of

1 members, they're all -- they're all cosmetic
2 companies of one -- one form or another, correct?

3 A Right. The -- yes.

4 Q And many of them are, in addition to
5 manufacturing and distributing cosmetics, they
6 also manufacture and distribute pharmaceuticals,
7 correct?

8 A Some do, yes.

9 Q Right. As an example, Johnson &
10 Johnson.

11 A Yes.

12 Q Right. And you're aware, are you not,
13 that the -- the FDA requirements as they relate to
14 pharmaceuticals are different than the FDA
15 requirements --

16 A Yes.

17 Q -- as they relate to cosmetics, correct?

18 MR. LOCKE: Objection. Beyond the
19 scope.

20 THE WITNESS: But I -- I'm aware of
21 that, yes.

22 BY MR. GOLOMB:

23 Q Just very generally, what -- based on
24 your many years of working at PCPC, how would you

1 explain the difference?

2 MR. LOCKE: Objection.

3 BY MR. GOLOMB:

4 Q Between the role of the FDA as they
5 relate to cosmetics versus pharmaceuticals.

6 MR. LOCKE: Objection. Beyond the
7 scope.

8 THE WITNESS: Pharmaceuticals are much
9 more -- there's a lot more regulation, and there's
10 premarket approval of pharmaceuticals. There's
11 not premarket approval of cosmetics.

12 BY MR. GOLOMB:

13 Q Is it fair to say that cosmetics are
14 self-regulated?

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 THE WITNESS: One -- one could say that,
18 but there are FDA -- a number of FDA regulations
19 involving packaging, labeling, ingredient
20 substantiation.

21 BY MR. GOLOMB:

22 Q Okay. And if you had read some of the
23 same documents that I read in preparation for the
24 deposition here today, it is -- as it relates to

1 regulation, it is the goal of the PCPC to maintain
2 that self-regulatory status, correct?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 THE WITNESS: We would have earlier said
6 that, but now we feel that our -- the goal is to
7 modernize regulation. People have accepted a
8 larger role for government agencies.

9 BY MR. GOLOMB:

10 Q What do you mean by that?

11 A I think there's a consumer expectation,
12 and we -- until perhaps ten years ago, we did use
13 the term "self-regulated" a lot. But we felt that
14 was no longer appropriate and that we needed to
15 work on modernizing regulation. For example, the
16 Food, Drug and Cosmetic Act which governs
17 cosmetics hasn't been changed since 1938.

18 Q Well, have you been on your website?

19 A Yes.

20 Q Have you been on your website to look at
21 it to prepare for your deposition here today?

22 A No.

23 Q Would it surprise you to see that on
24 your -- on your website they still refer to

1 self-regulation as a -- as a goal and a mission of
2 the PCPC as it relates to cosmetics?

3 MR. LOCKE: Objection to form.

4 THE WITNESS: That's -- I mean it's
5 possible. We're actually -- as I said earlier,
6 we're in the process of updating the website
7 anyway.

8 BY MR. GOLOMB:

9 Q Okay. So --

10 A But that probably is one area that's
11 being addressed.

12 Q So the -- the thinking as to the
13 self-regulatory status of the company began about
14 ten years ago, you said, but you just haven't
15 gotten to the website yet?

16 MR. LOCKE: Objection to form and beyond
17 the scope.

18 THE WITNESS: I -- I think, though, we
19 talk about modern -- you know, the goal of
20 modernizing government regulation.

21 BY MR. GOLOMB:

22 Q And -- and what do you mean by that?

23 A Updating federal regulation. We believe
24 in a strong regulatory process. FDA regulations

1 should be the gold standard, and we're hoping that
2 other regulatory bodies worldwide will model
3 themselves on FDA.

4 Q Well, and is that because the FDA
5 doesn't regulate cosmetics?

6 MR. LOCKE: Objection to form and beyond
7 the scope.

8 THE WITNESS: As I said, they -- there
9 is regulation, you know, involving how companies
10 have to label and package and disclose their
11 ingredients.

12 BY MR. GOLOMB:

13 Q Okay. What is your understanding of how
14 the FDA regulates labeling?

15 MR. LOCKE: Objection to -- beyond the
16 scope.

17 THE WITNESS: There's the Fair Package
18 Labeling Act, but it's really not my area of
19 responsibility. I'm just telling you what --
20 what -- more common knowledge.

21 BY MR. GOLOMB:

22 Q Okay. And -- well, is the -- is the
23 common knowledge based on what the employees of
24 the PCPC and its members would like it to be or is

1 it based on the actual regulation?

2 A It's based on the actual regulation.

3 Q Okay. Well, when was the last time you
4 looked at the actual regulation?

5 MR. LOCKE: Objection.

6 THE WITNESS: I don't recall.

7 MR. LOCKE: Beyond the scope.

8 BY MR. GOLOMB:

9 Q But you agree that whatever the
10 regulation is under the CFR is what's -- what is
11 binding on the company members --

12 A Yes.

13 Q -- of the PCPC, correct?

14 A Yes.

15 MR. LOCKE: Objection. Beyond the
16 scope.

17 MR. GOLOMB: Want to take about a
18 ten-minute break?

19 MR. LOCKE: Sure.

20 THE VIDEOGRAPHER: The time is
21 10:45 a.m., and we're going off the record.

22 (Recess.)

23 THE VIDEOGRAPHER: The time is
24 11:01 a.m., and we're back on the record.

1 BY MR. GOLOMB:

2 Q Mr. Pollak, do you have Pollak No. 3
3 in front of you there? This is the --

4 A Yes.

5 Q -- the ledger of the --

6 A Yes.

7 Q -- contributions.

8 Before I was asking you some questions
9 about whether or not certain entities received
10 payment, and you didn't know the answer to that.

11 And so my question to you is, who -- who
12 would know?

13 A Well, I assume Linda Loretz is covering
14 this, and the accounting department that produced
15 the document.

16 Q Okay. So your assumption is if I asked
17 her about the same people, Dr. Muscat,
18 Dr. Huncharek, Weinberg Group, et cetera, the
19 people I asked you about, and there's some
20 additional ones, that Ms. Loretz would be the one
21 to say, you know, in 2000 we received \$245,000 in
22 contributions from various task force members, and
23 I think Dr. Loretz would know the answer to how
24 much went to each of these individual entities; is

1 that correct?

2 A I assume so, yes.

3 Q Okay. We were also -- let's just talk
4 about -- you were saying about this -- although
5 the website hasn't been updated, this ten-year
6 transition going into self-regulatory based on
7 what the consumer wants.

8 First of all, who -- who -- which of the
9 employees that we talked about -- employee or
10 employees that we talked about on that
11 organizational chart would be the one who would be
12 most often liaisioning with the FDA?

13 A So it would depend on the issue. Tom
14 Myers on a lot of regulatory issues would -- or
15 Emily would be the primary --

16 Q Do you have -- I'm sorry. Do you have
17 the organizational chart in front of you?

18 A Sure. So some of it would be through
19 Science, some of it would be through legal, and
20 then some of it would be through government
21 relations, depending on the issue.

22 Q Okay. Let's -- let's talk about legal.

23 A Okay.

24 Q As it relates to the issue of talc, who

1 would be the person who would be the -- most often
2 liaisioning with the FDA?

3 A So I -- I don't think anyone from the
4 legal department did.

5 Q Okay. What about Government Affairs?

6 A They definitely did not.

7 Q You described for me before the
8 Government Affairs department as lobbying. So
9 you're saying that your lobbyists are not talking
10 to the FDA as it relates to talc?

11 A Correct.

12 Q And how is it that you're so sure about
13 that?

14 A I would have -- the government would be
15 more in the context of proposed regulation or
16 mainly for Government Affairs involving proposed
17 legislation.

18 Q Okay. And as -- as this ten-year
19 transition has been undergoing, have there -- has
20 there been legislation proposed?

21 A Yes.

22 Q Okay. And tell me about the
23 legislation.

24 A So this has started perhaps in 2008, an

1 effort to update and modernize the Food, Drug and
2 Cosmetic Act, to make some provisions of the
3 Voluntary Cosmetic Reporting Program mandatory, to
4 have FDA promulgate good manufacturing practices
5 for cosmetics, to formalize the Adverse Event
6 Experience Reporting System, things like that, and
7 then an ingredient review program.

8 Q Adverse event reporting for cosmetics?

9 A Mm-hmm. That's -- had initially been
10 part of the Voluntary Cosmetic Reporting Program,
11 so then that was eliminated around 1999.

12 Q Who was it that -- who is it at PCPC
13 that is responsible for that legislation?

14 A Well, there are a number of people who
15 work on it, but it would be John Hurson is the
16 EVP.

17 Q And he's EVP of what department?

18 A Govern -- Government Affairs.

19 Q Now, so you're -- you're saying that
20 John person -- I mean, John Hurson is -- is
21 responsible for this legislation, but he does not
22 have contact with the FDA?

23 A He has contact in the FDA. We've had
24 meetings regarding -- not recently, but regarding

1 the proposed legislation and what FDA -- how they
2 would handle it or how they would view it and what
3 would be acceptable to them.

4 Q And is the proposed legislation in
5 print?

6 A Yes. There's a -- it's been introduced
7 in the Senate.

8 Q Who has it been introduced by?

9 A Senators Feinstein and Collins.

10 Q That's SB what?

11 A I don't recall.

12 Q When was it first introduced?

13 A 2016, is it -- but within the last two
14 years.

15 Q And how did -- was it Mr. Hurson who got
16 Senators Feinstein and Collins aboard?

17 A Well, it was a broader effort, but yes.

18 Q Broader effort by who?

19 A Well, Lezlee Westine would have been
20 involved.

21 Q Was there involvement by some of your
22 members?

23 A Possibly, but I wouldn't -- I mean,
24 Senators Feinstein and Collins introduced the bill

1 on their own. We had been working with FDA on a
2 proposal that ended up in a stalemate, and then
3 Senator Feinstein decided to take the lead.

4 Q Does PCPC make contributions to
5 individual congressional members' campaigns?

6 A So there is a political action committee
7 and contributions would be made through that.

8 Q What's the name of the political action
9 committee?

10 A I think it's the PCPC Political Action
11 Committee.

12 Q And are they run out of the PCPC office?

13 A Yes.

14 Q And who is responsible for the day to
15 day of the PCPC PAC?

16 A So the federal PAC would be John Hurson.

17 Q So the same person who is responsible
18 for the proposed legislation is also responsible
19 for the PAC that maintains a political action
20 committee that makes contributions, in this case
21 to Senator Feinstein and Senator Collins?

22 MR. LOCKE: Objection to form.

23 THE WITNESS: Possible- -- I don't know
24 if -- I think --

1 BY MR. GOLOMB:

2 Q Are there -- are there separate
3 documents, financial documents for the PCPC PAC
4 that are maintained --

5 A Yes.

6 Q -- within the PCPC?

7 A Yes.

8 Q And is John Hurson the person that would
9 know the most about who contributed what to whom
10 and how much the PCPC contributed to which
11 legislators?

12 A Right. And there are annual filings
13 that I think are public.

14 Q And do you know what committee -- well,
15 strike that.

16 Do you know what -- what is the status
17 of the bill?

18 A Well, it's -- it's being considered in
19 the Senate Health, Education, Labor and Pensions
20 Committee.

21 Q Who's the chairman of that committee?

22 A Lamar Alexander.

23 Q Who is the minority leader?

24 A I don't recall.

1 Q Do you know who else --

2 A Maybe Patty Murray. I don't recall.

3 Q Do you know approximately when it --
4 approximately when it went to the Senate Health
5 Committee?

6 A So this is -- this year they're looking
7 at a draft.

8 Q And do you know which senators while
9 this is -- while this is pending before the
10 Senate, do you know which members received funds
11 from the PCPC PAC in the way of contributions?

12 A No, I don't.

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 BY MR. GOLOMB:

16 Q Do you know the names of any of the
17 sponsors to the bill?

18 A No.

19 Q Are there -- are there written reports
20 from Mr. Hurson from time to time about the status
21 of the legislation?

22 A Yes. We -- we report on it at our board
23 meetings.

24 Q How often are your board meetings?

1 A Three times a year.

2 Q When was the last time you had a board
3 meeting?

4 A May 31.

5 Q And did you receive a status of the
6 bill?

7 A Yes.

8 Q What was the status at that time?

9 A Approximately what I told you in the
10 last few minutes. It's being considered in -- in
11 the Senate Health Committee, and they're -- we're
12 hoping that Senator Feinstein and Senator
13 Alexander will get together and reach agreement,
14 and so far they haven't.

15 Q What -- is Senator Feinstein on the
16 Senate Health Committee?

17 A I think so, but I -- I don't know.

18 Q Okay. Do you know whether she's the --
19 the minority leader on that --

20 A I don't think she is.

21 Q -- committee?

22 Do you know why it is that Mr. Hurson
23 went to Senator Feinstein for -- to seek
24 co-sponsorship?

1 A He --

2 MR. LOCKE: Objection to form.

3 THE WITNESS: He didn't. As I said,
4 she -- she decided to introduce it on her own.

5 BY MR. GOLOMB:

6 Q Okay. And does the PCPC hire outside
7 lobbyists from time to time?

8 A Yes.

9 Q And do they hire outside lobbyists to
10 handle certain issues?

11 A We have a lobbying firm on retainer.

12 Q Who is that?

13 A Mehlman Vogel Castagnetti Thomas or --
14 they may have changed the name, but that's --

15 Q I'm sorry, Melvin?

16 A Mehlman.

17 Q Mehlman.

18 A M-E-H-L-M-A-N.

19 Q Mark Mehlman?

20 A No, Bruce Mehlman. No relation.

21 Q What was the second name?

22 A Well, they -- I know David Castagnetti
23 is one of the other named partners. They changed
24 their name, and I don't want to give you the

1 wrong --

2 Q Okay. And do you know who is on the --
3 from the outside lobbying team that is responsible
4 for this senate bill?

5 MR. LOCKE: Objection to form and beyond
6 the scope.

7 THE WITNESS: I -- I wouldn't say the
8 person -- we work with Bruce Mehlman and get his
9 advice.

10 BY MR. GOLOMB:

11 Q When was the last time you spoke with
12 Bruce Mehlman about this bill?

13 A I saw him at a meeting in the last few
14 weeks.

15 Q And did you talk about this bill?

16 A Yes.

17 Q Was that the purpose of the meeting?

18 A Yes.

19 Q Okay. When you say you have them on
20 retainer, how much is the retainer?

21 A I think it is \$25,000 a month.

22 Q And where does the money come from?

23 A From our general operating budget.

24 Q Are outside lobbyists hired from time to

1 time to deal with specific issues related to a
2 specific task force?

3 A I wouldn't say a specific task force.
4 Sometimes it's a specific piece of legislation.

5 Q Are there -- are there times when the
6 funding of the outside lobbyists, like in the case
7 of Mehlman and his \$25,000 a month, are there
8 times when the money would come from an individual
9 task force rather than the operating?

10 A I don't think so.

11 Q What do you hope to accomplish through
12 the passage of this bill?

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 THE WITNESS: As I said, you know, the
16 goal is modernize federal regulation and make
17 mandatory a number of things that are currently
18 voluntary; have GMPs as part of the mandatory
19 regulation so that the FDA is considered the gold
20 standard as far as cosmetic regulation.

21 BY MR. GOLOMB:

22 Q Give me an example of something that is
23 currently now mandatory that you want to make -- I
24 mean that is now voluntary that you want to make

1 mandatory as part of this bill.

2 MR. LOCKE: Objection. Beyond the
3 scope.

4 THE WITNESS: Currently, companies --
5 there's a voluntary program to -- for companies to
6 provide locations of their manufacturing
7 facilities as well as ingredient -- the formulas
8 for cosmetic products, and they do register those
9 with FDA, but it's not mandatory.

10 BY MR. GOLOMB:

11 Q And why do you want that to be mandatory
12 for your members?

13 MR. LOCKE: Objection. Beyond the
14 scope.

15 THE WITNESS: Because we think it's a
16 stronger regulatory system.

17 BY MR. GOLOMB:

18 Q Okay. Well, on your website you refer
19 to the need to maintain a self-regulatory system,
20 so which common sense-wise doesn't seem to jibe.

21 So tell me -- I mean you mentioned to me
22 before that there's been this ten-year transition,
23 but it's still on your website.

24 A Right. We still -- for example, the

1 Cosmetic Ingredient Review program is the linchpin
2 of our self-regulatory philosophy. So -- and
3 we're not -- we're not disavowing that. That's
4 going to be a key.

5 Q And when you say that's the linchpin of
6 your self-regulatory process, what do you mean?

7 A Currently there's no FDA premarket
8 review of cosmetics or cosmetic ingredients. The
9 proposed legislation would have set up an
10 ingredient review process, but we have this
11 self-regulatory program for 40 years where we
12 review the -- the data on the safety of cosmetic
13 ingredients, and the expert panel makes
14 recommendations as far as determination of the
15 safety category.

16 Q So in part, are you saying that you --
17 you have this CIR, number one, to maintain
18 independence from the PCPC and while at the same
19 time strengthening the self-regulatory process?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: I'm not sure I would
22 characterize the legislation as strengthening the
23 self-regulatory process.

24 BY MR. GOLOMB:

1 Q I -- I didn't say -- I'm sorry.

2 A Okay.

3 Q I didn't say anything about the -- I'm
4 talking about the CIR.

5 A Okay.

6 Q You said it's the linchpin of your
7 self-regulatory process, and my question to you
8 was, do you -- you've -- this linchpin of the
9 self-regulatory process, you review that as
10 some -- something independent from the PCPC?

11 MR. LOCKE: Objection to form.

12 THE WITNESS: Yes. I mean, the -- the
13 expert panel is totally separate.

14 BY MR. GOLOMB:

15 Q The expert panel which is selected by
16 employees of the PCPC, correct?

17 A No.

18 Q You have -- there's a CIR board of
19 directors?

20 A No.

21 Q There -- is there a CIR board of some
22 sort?

23 A No, there's a CIR steering committee
24 that's in the procedures that are on their

1 website, and the CIR expert panel members are --
2 there's a nominating process. Anybody -- any
3 member of the public can nominate someone for --
4 to be considered for an expert panel member.
5 There are other ways of soliciting nominations,
6 and the ultimate determination is made by the
7 steering committee.

8 Q How many members of the steering
9 committee are there?

10 A Seven.

11 Q And is there a chairman of the steering
12 committee?

13 A Yes.

14 Q And who is the chairman of the steering
15 committee?

16 A So the chairman of the steering
17 committee is the CEO of PCPC.

18 Q All right. And so that's your -- that's
19 your view of independence, to have the -- the --
20 the chairman of the company that's funding the
21 organization, in this case the CIR, be the
22 chairman of what it is they're funding?

23 MR. LOCKE: Objection to form.

24 THE WITNESS: The steering committee

1 also includes a representative from the Society of
2 Toxicology, the American Academy of Dermatology,
3 there's a representative from the Consumer
4 Federation of America. It's, you know, all -- all
5 the stakeholders involved with -- in the program
6 have a say.

7 BY MR. GOLOMB:

8 Q Yeah. And all those stakeholders are --
9 are selected to serve as members of the steering
10 committee by executives from PCPC, correct?

11 MR. LOCKE: Objection. Form.

12 THE WITNESS: No. The -- in fact, we
13 just -- we're in the process of getting a new
14 toxicologist, and there is -- you know, the
15 Society of Toxicologists is putting forth some
16 recommendations on people, and it will be
17 considered at the next steering committee meeting.

18 BY MR. GOLOMB:

19 Q Okay. Can we go to Exhibit 11, please.

20 MR. DONATH: 11?

21 MR. GOLOMB: 11.

22 (Pollak Exhibit No. 11 was marked
23 for identification.)

24 BY MR. GOLOMB:

1 Q What you have in front of you is Imerys
2 document 118791, and if you look at the bottom
3 half, it says: "Part B. The Cosmetic Ingredient
4 Review Steering Committee and Staff."

5 A Mm-hmm.

6 Q Are you familiar with this document?

7 A Yeah. I mean it's -- it's an old
8 version of the procedures.

9 Q Okay. And when you say old, how old is
10 it?

11 A Well, it's at least a few years old
12 because it still has on -- on there 1101 17th
13 Street, and we moved four-and-a-half years ago.

14 Q Okay. Well, if you look at Section 10,
15 it's defined as "Organization of the Cosmetic
16 Ingredient Review, "and look at (a)(1) through
17 (6) --

18 A Mm-hmm.

19 Q -- other than the address, has any of
20 that changed substantively?

21 A Yeah, so the only other change would be
22 in (a)(1), the president and CEO can designate the
23 chief operating officer as the chair of the
24 steering committee.

1 Q Okay. And so for the record, this is
2 the organization of the Cosmetic Ingredient
3 Review. And it says: "The general policy and
4 direction for Cosmetic Ingredient Review shall be
5 given by a steering committee. A quorum of the
6 steering committee shall consist of five members.
7 Any member before the steering committee shall be
8 decided by a majority vote of the CIR members
9 present at the time, except where otherwise
10 specifically provided in these procedures. The
11 steering committee shall consist of the following
12 members."

13 First of all, did I read that correctly
14 so far?

15 A Yes.

16 Q And is this document, is this from the
17 PCPC or from the Cosmetic Ingredient Review?

18 MR. LOCKE: Objection. Just to the
19 extent to -- I want to state for the record this
20 is an old version. We have and can give you a
21 current version if you want.

22 You can answer the question.

23 THE WITNESS: Right. So as he said, I
24 mean I reviewed the procedures on their website

1 yesterday.

2 BY MR. GOLOMB:

3 Q Is this -- what you have in front of
4 you, is this a procedure from the CIR or a
5 procedure from the PCPC?

6 A It's on the -- it's on the CIR website.

7 Q Okay. And is the CIR website distinct
8 from the PCPC website?

9 A Yes.

10 Q And who -- who actually -- who is the
11 webmaster of the CIR website?

12 A So that would be both Bart and Kevin
13 Fries, who is on their organization chart.

14 Q Okay. On the organization chart of the
15 CIR?

16 A Yes.

17 Q And they -- they're both paid employees
18 of the PCPC, correct?

19 A Yes.

20 Q All right. And so this lists six
21 members of the steering committee. "The president
22 and CEO of the council" -- by that it means the --
23 the PCPC council, correct?

24 A Yes.

1 Q -- "who shall serve as the chair of the
2 steering committee." Right?

3 A Yes.

4 Q So the chair of the steering committee
5 for the CIR is the president and CEO of PCPC.

6 A Right. And the revision is that the
7 chief operating officer can serve as the chair.

8 Q In addition to the president and CEO or
9 instead of?

10 A Instead of.

11 Q And then it says: "A dermatologist who
12 shall represent the American Academy of
13 Dermatology."

14 A Mm-hmm.

15 Q Correct?

16 A Yes.

17 Q And how is that person selected?

18 A Well, the American Academy of
19 Dermatology nominated Dr. Wilma Bergfeld, who
20 serves as the chair of the expert panel also.

21 Q And does --

22 A She's the former president.

23 Q Does the -- does the CIR have final say
24 on whether -- who that member of the American

1 Academy of Dermatology may be?

2 A Well, the steering committee does.

3 Q Right. The steering committee that's
4 chaired by the --

5 A Right.

6 Q -- president and CEO or COO of --

7 A Correct.

8 Q -- the PCPC.

9 And is the same true of the
10 toxicologists, that is that the PCPC has the final
11 say?

12 MR. LOCKE: Objection to form.

13 THE WITNESS: The steering committee
14 does.

15 BY MR. GOLOMB:

16 Q All right. And the -- the chair of
17 the -- it says: "(4) The chair of the council's
18 CIR Science and Support Committee." Who is that?

19 A So I actually -- the position may be in
20 transition. The person before was -- was Jack
21 Linard, but I don't know if we consider him --
22 it's the vice chair of SAC Exec, Espe Troyano from
23 Proctor & Gamble.

24 Q Okay. Well, whoever the individual is,

1 the chair of the council's CIR Science and Support
2 Committee are PCPC employees, correct?

3 A No.

4 Q Who are they?

5 A I just said she's Espe Troyano from
6 Procter & Gamble.

7 Q Okay. And they are a member of the -- a
8 dues paying member of the PCPC?

9 A Yes.

10 Q And the council executive vice president
11 for Science --

12 A Right.

13 Q -- when you refer to the council, you're
14 referring to the PCPC?

15 A Yes.

16 Q Okay. An employee of the PCPC is the
17 fifth member of this steering committee.

18 A Yes.

19 Q And then a consumer representative who
20 shall represent the Consumer Federation of
21 America, how is that person selected?

22 A The Consumer Federation of America
23 nominates someone.

24 Q And then this steering committee has the

1 final say on who that will be?

2 A Mm-hmm.

3 Q Yes?

4 A Yes.

5 Q And from time to time is the person who
6 is actually appointed to the committee some --
7 somebody who is different than the consumer
8 representative that may be nominated by the
9 Consumer Federation of America?

10 A Most of the time it's the same person.

11 Q But you said "most of the time." Not
12 all the time.

13 A There may have been -- I don't know in
14 the past whether there's ever been someone
15 different. It probably has always been the same
16 one, but it doesn't have to be.

17 Q Okay. You -- you referred to -- when I
18 was asking you about the legislation before, you
19 talked about board meetings that were held three
20 times a year, the most recent one was May 31st.

21 A Yes.

22 Q Those are board meetings of the PCPC?

23 A Yes.

24 Q And are there minutes of those board

1 meetings?

2 A Yes.

3 Q Who maintains those minutes?

4 A I do.

5 Q Did you review those -- any of those
6 minutes to help prepare you for your deposition
7 today?

8 A No.

9 Q Where are those board meetings held?

10 A Most of the time they're in New York
11 City. We have a board meeting in conjunction with
12 our annual meeting, which is usually held in
13 Florida. So two of the three are in New York.

14 Q Let's talk about the PCPC relationship
15 with -- with J&J. We've already talked about
16 their contributions to the task force.

17 They're also a member of the PCPC,
18 correct?

19 A Correct.

20 Q And as I understand from your website,
21 there are approximately 600 members?

22 A Right, including the associate members
23 who are the suppliers.

24 Q Now, is -- has that number been updated

1 over the last ten years or is that a ten-year-old
2 number?

3 A It's approximately the same. I mean, in
4 a given year we may be higher than 600 or lower --
5 but it's -- it's approximately the same over
6 the --

7 Q And does the website get updated --

8 A Yes.

9 Q -- on an annual basis to -- to show the
10 numbers?

11 A We -- we don't put an exact number
12 because at any given time during the year, the
13 number may be higher or lower. Sometimes we have
14 608, sometimes we have 592. So that's why we say
15 approximately 600.

16 Q Okay. And I would imagine that there's
17 information on your website that changes more than
18 once a year.

19 A Oh, yeah.

20 Q Okay. And -- and when information
21 becomes -- when there's new information that may
22 be relevant to the website, the website is
23 updated?

24 A Yes.

1 Q And so -- I'm sorry, I may have asked
2 you this already, but the -- who is the -- kind of
3 the webmaster of the PCPC website?

4 A So currently it's Natasha Clover. But
5 we are -- as part of the website redesign process,
6 Jamie Kirk, who is in Public Affairs, will also be
7 working with her on updating features on the
8 website.

9 Q And does the website have -- is there a
10 blog on the website?

11 A No.

12 Q Is there information on the website that
13 changes or is added on a weekly basis?

14 A Could be, because we have different
15 meetings and events posted that way. And then if
16 we do a press release, but the -- the press
17 releases wouldn't be -- most of the time wouldn't
18 be more than once a month.

19 Q And the -- the -- is there a roster of
20 the members of the PCPC somewhere on the website?

21 A Yes.

22 Q And I imagine that changes from time to
23 time?

24 A Yes.

1 Q And when -- when -- when that roster
2 changes from time to time, is it changed on the
3 website?

4 A Yes.

5 Q What other kinds of things are changed
6 on a, you know, regular, weekly, monthly,
7 bimonthly basis on the website?

8 A So on the public website, that -- that's
9 the majority of it would be involving meetings and
10 upcoming events, webinars.

11 Q Okay. So as I understand it from your
12 previous deposition, there are two different kinds
13 of members; is that correct?

14 A Right.

15 Q And what are they?

16 A Active members are manufacturers and/or
17 distributors of finished products. Associate
18 members are the suppliers to them.

19 Q Okay. And so for our purposes, J&J is
20 an active member?

21 A Yes.

22 Q And Imerys --

23 A Would be an --

24 Q -- if they're still a member --

1 A Right, would be an associate.

2 Q -- is an associate member.

3 And how -- how's their dues structure
4 determined?

5 A Okay. So for active members, dues are
6 on a sliding scale based on their U.S. sales of
7 cosmetics, toiletries and fragrances.

8 The associate members has different
9 ways -- for Imerys, for an ingredient supplier, it
10 is a sliding scale based on their U.S. sales of
11 ingredients to the cosmetics industry.

12 Q So --

13 A With a -- with a cap on what they would
14 pay.

15 Q Okay. And so what did -- what did J&J
16 pay for membership last year?

17 A If I recall, it was a little -- it was
18 in the \$490,000 range.

19 Q Is there any company that pays more than
20 them?

21 A Yes.

22 Q Who?

23 A Well, it's considered confidential
24 information we tell companies on the dues form.

1 There are at least five companies that pay more.

2 Q And out of those five companies, what --
3 what's the highest dues amount?

4 A I think the -- our largest member is
5 paying over 1.1 million a year now. The second
6 largest would be 900-something, and then two
7 companies in the 700s and one in the 600s.

8 Q And has J&J been a member at least since
9 you've been with the company?

10 A Yes.

11 Q And again, that's how many years?

12 A Thirty-five.

13 Q And if we looked at a -- if we looked at
14 a graph over the last 35 years, approximately how
15 much on an annual basis does J&J pay?

16 MR. LOCKE: Do you mean by percentage?

17 MR. GOLOMB: No. He gave me --

18 THE WITNESS: So they -- they --

19 BY MR. GOLOMB:

20 Q I'm sorry, let me be clear.

21 You gave me an amount of \$490,000 for
22 last year, and so if we look back 35 years, has
23 that been a pretty steady number? Has it gone --
24 has it fluctuated?

1 A It's gone up substantially.

2 Q From what to what?

3 A I think they -- in the '80s they
4 probably paid in the \$40,000 range -- forty,
5 50,000. They were a much smaller -- much smaller
6 company in this space, and during that time they
7 acquired a lot of other major brands that they pay
8 dues on. For example, Neutrogena cosmetics,
9 Aveeno, Listerine mouthwash, et cetera.

10 Q And when did that change?

11 A A different -- different year. I don't
12 know which acquisition was which year.

13 Q But you said in the '80s, they were
14 paying about forty to \$50,000 a year, and --

15 A Right. And starting in the '90s, they
16 had -- there were a series of acquisitions.

17 Q And were they -- so what were they
18 paying? Just generally, and we're not holding you
19 to --

20 A And, again, there have -- there have
21 been some dues rate increases. But I would say
22 ten years ago, they were probably paying two, 250.

23 Q Okay. And in the last ten years?

24 A I think their dues have gone up because

1 they're -- the -- the number of brands they're
2 paying on has increased in the U.S.

3 Q Is it fair to say that over the last 30
4 years that, just using your kind of loose range of
5 numbers, that J&J has paid in excess of \$15
6 million in -- in dues?

7 A I think that's --

8 Q Does that sound about right?

9 A I think that's probably on the high
10 side.

11 Q Well, what would you say?

12 A If -- I would say the average would be
13 no higher than \$200,000 a year, and probably less.
14 So for 30 years, doesn't that put us below
15 6 million?

16 Q And then that doesn't cover what they
17 paid into the task force, correct?

18 A Yes. That's separate.

19 Q Right. And -- and any other task force
20 they may be contributing into that we haven't
21 talked about.

22 A Right.

23 Q And do we know whether or not there are
24 other task forces that they're involved in?

1 A Yes, there are.

2 Q How many?

3 A I don't know how many, but I know they
4 would have made substantial contributions to the
5 sunscreen task force because that's a major
6 category for them.

7 Q When you say "major contribution," how
8 much are we talking about?

9 A 100,000, 200,000. I don't recall.

10 Q And how long has that been active --

11 A Sunscreen task force?

12 Q Yeah.

13 A I'd say 20 years.

14 Q And have they been paying a hundred to
15 \$200,000 --

16 A No, it's not --

17 Q -- for 20 years?

18 A It's not an annual assessment. Again,
19 it's as needed to fund the activities, and there
20 are not solicitations every year.

21 Q How many active years have there been
22 over the last 20 years for the sunscreen
23 committee?

24 A I really don't know off the top of my

1 head.

2 Q Is it more than half?

3 A Probably.

4 Q Okay. Who is the person -- if you know,
5 who is the person from J&J who is the main contact
6 with the task -- the Talc Interested Party Task
7 Force?

8 MR. LOCKE: Objection. Beyond the
9 scope.

10 THE WITNESS: I don't know.

11 BY MR. GOLOMB:

12 Q Let's talk a little bit about Imerys and
13 their -- their contributions, both to the task
14 force as well as to the PCPC.

15 Have they been members as long as
16 you've -- whether or not it was Imerys, Luzenac,
17 Rio Tinto, have they been members since you've
18 been around?

19 MR. DONATH: Objection to the form.

20 THE WITNESS: Probably, but I -- I don't
21 have independent knowledge. I did not check that.

22 BY MR. GOLOMB:

23 Q Okay. And how much in dues did they pay
24 last year?

1 A I would -- it was certainly under
2 \$10,000, and it may have been a few thousand.

3 Q And that is exclusive of whatever amount
4 they may have contributed to the task force?

5 A Yes.

6 Q And has their -- their -- their dues
7 structure been pretty straight --

8 A Again, there's been some dues rate
9 increases, but it's not dramatically different
10 over the years.

11 Q What -- what would it have been on the
12 low end?

13 A 2,000. I don't know.

14 Q Okay. And you know who the National
15 Cancer Institute is, correct?

16 A Yes.

17 Q And does the PCPC have communications
18 from time to time with the National Cancer
19 Institute?

20 A Not that I'm aware of. We may be on a
21 distribution list that we receive something from
22 them, but I'm not aware of any particular
23 relationship.

24 Q Okay. If --

1 MR. LOCKE: Let me just -- we prepared a
2 document based on some of the questions for the
3 entities that were listed on the notice, and so we
4 just put the financial portion, which is what
5 Mr. Pollak would be testing -- testifying about
6 on here.

7 MR. GOLOMB: All right. What exhibit
8 are we up to, putting 11 aside?

9 THE REPORTER: Four.

10 MR. GOLOMB: Four? Okay, 4.

11 (Pollak Exhibit No. 4 was marked
12 for identification.)

13 MR. GOLOMB: Does he have a copy to --

14 MR. LOCKE: I'll give you a copy.

15 I tell you what, just so we keep the
16 record clear, why don't you give him that copy,
17 and I'll give you this copy.

18 MR. GOLOMB: Yeah, okay.

19 BY MR. GOLOMB:

20 Q Okay. Are you familiar with this
21 document that's in front of you, Exhibit 4?

22 A Yeah. Tom Locke showed it to me this
23 morning.

24 Q Okay. Do you know who prepared this

1 document?

2 A I actually don't.

3 Q Have you ever -- do you know what --
4 what information or documents was used to prepare
5 this?

6 A I assumed he consulted with our
7 accounting department to get the information.

8 Q Okay. So Mr. Locke would be
9 communicating with your accounting department
10 without your knowledge?

11 A Or it may have been with the knowledge
12 of Tom Myers, but it wasn't specifically through
13 me.

14 Q Okay. And you saw this for the first
15 time when?

16 A This morning.

17 Q Okay. And what does this document
18 purport --

19 A I know the -- the information was
20 covered in the interrogatories, and that they
21 had -- in order to respond to the interrogatories,
22 they had to put together this information.

23 Q Okay. Well, if this information was in
24 the answers to interrogatories, then why would we

1 need a separate document?

2 MR. LOCKE: I can answer it, because
3 your notice is broader than the interrogatories,
4 and we wanted to cover all the information. And
5 also based on some questions that were asked to
6 Ms. Loretz about non-talc-related contributions to
7 entities.

8 BY MR. GOLOMB:

9 Q And -- and so do you know what this
10 document purports to be?

11 A Yes.

12 Q What?

13 A Pay- -- any payments we would have
14 made -- that PCPC would have made to these
15 organizations.

16 Q Okay.

17 A And I think there -- there were only --
18 our accounting system only has records
19 electronically or whatever back to 2002.

20 Q Well, let -- let's go through this, and
21 that -- so does the PCPC have a relationship other
22 than a financial relationship with the National
23 Academy of Sciences?

24 A No, I don't even think we have a

1 financial relationship.

2 Q Well, that wasn't my question. My
3 question was --

4 A No, no relationship.

5 Q Okay. And does the -- if we assume for
6 the sake of discussion that these numbers are
7 accurate, it says with respect to these various
8 organizations that there have been no talc-related
9 payments, correct?

10 A Yes.

11 Q Okay. There -- there are some other
12 payments that have been made, and it says "i.e.,
13 charity and dues." Do you see that?

14 A Yes.

15 Q So as an example, \$90,700 of other
16 payments made to the American Cancer Society. Do
17 you know what those payments were made for?

18 A So it would be a mixture of things
19 because the American Cancer Society is a partner
20 with the Look Good Feel Better foundation on
21 producing -- on running the Look Good Feel Better
22 program. Also they had shared the proceeds of the
23 DreamBall.

24 So there may have been a reconciliation

1 of funds after the event, and there are different
2 things in our partnership agreement which, you
3 know, identifies who pays for certain printing
4 things, and I assume it was to reconcile accounts
5 per the agreement. There also may have been -- we
6 may have purchased seats at the DreamBall,
7 DreamBall tickets for certain staff members over
8 the years.

9 Q And the -- under the Consumer
10 Federation -- federal --

11 A So it should be Consumer Federation of
12 America.

13 Q Right. There were no talc-related
14 payments, but there were 367,000 and change of
15 other payments made between 2002 and 2018,
16 correct?

17 A Yes.

18 Q Okay. You would agree with me, would
19 you not, that you could have a relationship with
20 one or more of these companies that has nothing to
21 do with finances?

22 A Yes.

23 Q All right. And so do you know one way
24 or the other whether or not the PCPC has such a

1 relationship with the National Cancer Institute?

2 A I'm not aware of any, and it's never
3 come up.

4 Q All right. Who -- if such a
5 relationship existed, who would know that?

6 A I assume someone in the Science
7 department.

8 Q Okay. Linda Loretz, perhaps?

9 A Perhaps.

10 Q Okay. Because I would assume, correct
11 me if I'm wrong, that, as an example, the National
12 Cancer Institute may -- may be circulating
13 information through a study, through periodicals,
14 through their website that may have effect on some
15 of your members.

16 MR. LOCKE: Objection. Beyond the
17 scope. And form.

18 THE WITNESS: I -- it's possible. I
19 don't know.

20 BY MR. GOLOMB:

21 Q Okay. Let's go back to the cosmetic
22 industry review, the CIR.

23 We talked a lot about the administration
24 of the CIR, we talked a lot about the funding of

1 the CIR, the management of the CIR in terms of the
2 steering committee.

3 How are -- how are issues that get in
4 front of the CIR determined? Is it determined by
5 the -- by the -- by the steering committee?

6 MR. LOCKE: Objection. Beyond the
7 scope.

8 THE WITNESS: So I'm not sure what you
9 mean by issues. If you mean what ingredients are
10 they reviewing?

11 BY MR. GOLOMB:

12 Q Right.

13 A So there is a priority list that is
14 developed, and I think that's actually noted in
15 the procedures also. If not, it's explained on
16 their website. The priority list is based on
17 the -- how often an ingredient is used based on
18 the voluntary reporting program data on cosmetic
19 ingredient -- formulations and ingredients.

20 Q I know you answered this before, but
21 just refresh my memory, when was it that the CIR
22 was formulated?

23 A I think in 1976.

24 Q And why was it formulated?

1 A It was at a time where there was a lot
2 of legislation being considered in Congress that
3 would have mandatory, more stringent oversight of
4 the industry, and so we got together with Consumer
5 Federation of America and others and came up with
6 a -- with a voluntary reporting program, the idea
7 of international nomenclature, for uniform
8 nomenclature for cosmetic ingredients, and then a
9 review program for cosmetic ingredients that was
10 modeled on the FDA OTC drug review process.

11 Q Okay. And how -- how was it determined
12 what -- what ingredients will be reviewed by the
13 CIR?

14 MR. LOCKE: Objection. Form, beyond the
15 scope.

16 THE WITNESS: So that's where we go back
17 to the priority list based on indications of use
18 by what companies are filing with the FDA under
19 the voluntary program. Also there's a way for FDA
20 to petition and ask CIR to review ingredients, and
21 I think there's a consumer -- you know, an outside
22 group can come in and petition for review.

23 BY MR. GOLOMB:

24 Q Okay. And that petition could be either

1 accepted or denied, correct?

2 A Correct.

3 Q And so -- and ultimately those decisions
4 are made by the CIR steering committee.

5 A Right. And the steering committee
6 publishes the priority lists and everything is
7 transparent. And the meetings are open.

8 Q Okay. When you say "the meetings are
9 open," are there -- there are meetings to
10 determine what -- what ingredients will be
11 reviewed and what ingredients will not be
12 reviewed?

13 A So the actual meetings where they're
14 reviewing the literature and making the
15 determinations are open. When the priority list
16 is developed, I think it is presented at -- I
17 think they present the priority list for the year,
18 and I think that is subject to comment by anybody
19 in attendance at the meeting.

20 Q Okay. And are there minute -- minutes
21 of these meetings?

22 A Yes.

23 Q And how often do these minutes --
24 meetings occur?

1 A Four times a year.

2 Q And where are these meetings?

3 A Washington, D.C.

4 Q And who is specifically invited to these
5 meetings?

6 A They're open to the public, and they --
7 per the procedures, there is a notice put out and
8 posted on their website and circulated in the
9 trade.

10 Q Listed on the CIR website?

11 A Yes.

12 Q When is the next meeting?

13 A September 24th, I think.

14 Q Where?

15 A Washington -- they're held at hotels.

16 Q Okay. Where's that particular meeting
17 being held?

18 A I don't remember if it's the Madison
19 Hotel or not. That's where the last one was.

20 Q Okay. And since its inception, do you
21 have any idea of how many ingredients have been
22 reviewed by the CIR?

23 MR. LOCKE: Objection. Beyond the
24 scope.

1 THE WITNESS: Several thousand.

2 BY MR. GOLOMB:

3 Q Would you be surprised to know that the
4 number is -- is somewhere north of 5,000?

5 A No, I --

6 Q And out of those 5,000 or so ingredients
7 that have been reviewed, would you surprise -- be
8 surprised to know that 13 of them have been
9 concluded to be unsafe?

10 MR. LOCKE: Objection to form and beyond
11 the scope.

12 THE WITNESS: Yeah, that sounds
13 approximately right.

14 BY MR. GOLOMB:

15 Q Okay. So the -- the CIR, which is
16 maintained by the PCPC, has found that less than
17 .0025 percent of the ingredients that it has
18 reviewed to be unsafe for consumer use; is that
19 correct?

20 MR. LOCKE: Objection to form and beyond
21 the scope.

22 THE WITNESS: Well, I haven't done the
23 math.

24 BY MR. GOLOMB:

1 Q Okay. If I told you I have done the
2 math, would you trust me?

3 MR. LOCKE: Objection to the form.

4 (Laughter.)

5 BY MR. GOLOMB:

6 Q Let's take a look at some documents.

7 Now, you told us that in the -- that the
8 last -- well, first of all -- strike that.

9 You -- and this is a little confusing to
10 me, so maybe you can help me out. You told us on
11 the one hand that over the last ten years or so
12 that the PCPC and its members are transitioning
13 from this desire to be self-regulatory to no
14 longer being self-regulatory.

15 In the simplest terms, is that what you
16 told me?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 THE WITNESS: So I think that's a little
20 bit of a mischaracter-- -- characterization.

21 I think the -- the movement is towards a
22 little more mandatory regulation, but it's based
23 on consumer research that consumers are looking
24 for that, have that expectation.

1 BY MR. GOLOMB:

2 Q Okay. Well, I'm wondering, were you --
3 since -- I don't know if you -- if you know this,
4 but because you told us that you didn't review --
5 sorry, you did not review the website in
6 preparation for your deposition.

7 So I wonder if you agree or disagree
8 with the statement that says: "The CTFA strongly
9 opposes the attempt to remove the self-regulatory
10 status of the cosmetic industry."

11 Is that an accurate statement?

12 A We wouldn't have used --

13 MR. LOCKE: Objection. Form and beyond
14 the scope.

15 Go ahead.

16 THE WITNESS: If we're saying CTFA, then
17 it's a very outdated document because the name
18 changed.

19 BY MR. GOLOMB:

20 Q When did the name change from CTFA
21 change to -- to PCPC?

22 A January 1, 2008.

23 Q Okay. So it's at the time -- around the
24 time that the CTFA changed its name to the PCPC

1 was around the time that the -- they were
2 transitioning from this group that -- that
3 strongly opposed anything other than a -- a
4 self-regulatory status, that's a quote, of the
5 cosmetic industry to being more of a mandatory
6 regulation?

7 A I would say that was --

8 MR. LOCKE: Hang on.

9 Objection to form, beyond the scope.

10 THE WITNESS: That was part of it. It
11 was part of the same consumer -- the reason we
12 changed the name was also based on consumer
13 research.

14 BY MR. GOLOMB:

15 Q Consumer research done by who?

16 A Different outside groups, not any of the
17 groups involved with this.

18 Q And you're familiar with Proposition 65?

19 A Yes.

20 Q What is Proposition 65?

21 MR. LOCKE: Objection. Beyond the
22 scope.

23 THE WITNESS: It's a -- it's a
24 California ballot initiative that was passed that

1 requires warning labels on various consumer
2 products that are -- have any association with the
3 possibility of being a carcinogen.

4 BY MR. GOLOMB:

5 Q Okay. And you're aware, are you not,
6 that when that was voted on by the voters of
7 California back in 1986 that the PCPC and its
8 members spent over \$600,000 to defeat that bill,
9 correct?

10 MR. LOCKE: Objection to form, beyond
11 the scope.

12 THE WITNESS: I -- I know we opposed it.
13 I -- I don't know how much we spent on that.

14 BY MR. GOLOMB:

15 Q Okay. So then, am I to then understand
16 your testimony here today that if that same
17 initiative was -- was seeking passage, that the
18 PCPC position with respect to Proposition 65 would
19 be different?

20 MR. LOCKE: Objection to form, beyond
21 the scope.

22 THE WITNESS: No.

23 BY MR. GOLOMB:

24 Q It would be the same?

1 A Yeah.

2 Q They would want defeat of that bill?

3 MR. LOCKE: Objection to form and beyond
4 the scope.

5 BY MR. GOLOMB:

6 Q Correct?

7 A Probably.

8 Q Okay.

9 MR. GOLOMB: What are we -- around 5?
10 Exhibit 5.

11 (Pollak Exhibit No. 5 was marked
12 for identification.)

13 BY MR. GOLOMB:

14 Q This is a PCPC document 52417, which
15 we've marked as Exhibit 5, and it is a CTFA
16 Mission Statement. And there's a -- it's a
17 composite document that we will look at some of
18 the pages of.

19 Have you seen this before?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: I'm sure I have, but
22 again, it's at least ten years old.

23 BY MR. GOLOMB:

24 Q Do you know when this document was

1 created?

2 A Not specifically, but I would imagine
3 between 2005 and 2007.

4 Q Okay. And certainly before that time,
5 the issue of talc and ovarian cancer was -- was an
6 issue of concern for the CFTA, correct?

7 A For CTFA?

8 Q CTFA.

9 A But it was one of many.

10 Q Well, I understand, but --

11 A Yeah.

12 Q -- it was -- I mean, in fact, sunscreen
13 was another one at that time that was an issue --
14 it was one of many, but it was an issue to --

15 A Mm-hmm.

16 Q -- its members, particularly Imerys and
17 J&J.

18 A Mm-hmm.

19 MR. DONATH: Objection.

20 MR. LOCKE: You need to say --

21 THE WITNESS: Yes.

22 BY MR. GOLOMB:

23 Q Do you know who Dr. Alfred Wehner is?

24 A No.

1 Q Do you know who the Biomedical
2 Environmental Consultants are?

3 A No.

4 Q Okay. So you -- you haven't seen any of
5 the communications between the CTFA and -- well,
6 you know who Stephens -- strike that.

7 You know who Stephen Gettings is, right?

8 A Yes.

9 Q So you haven't seen any of the documents
10 and the communications between Stephen Gettings
11 and Dr. Wehner beginning in 1993?

12 A It's possible I did in preparation for
13 the last deposition. I looked at a lot more
14 documents. But in -- since it's been almost three
15 years, I can't recall specifically which documents
16 I looked at.

17 Q Okay. And so you're unaware of the
18 retention of Dr. Wetting -- Dr. Wehner by
19 Dr. Gettings to deal with the talc/ovarian cancer
20 issue?

21 MR. LOCKE: Objection to form and beyond
22 the scope.

23 THE WITNESS: I'm familiar with the
24 name. I know the name has come up, but more than

1 that, I can't be sure.

2 BY MR. GOLOMB:

3 Q Okay. And when you say you know that
4 it's come up, how do you know that?

5 A The name is familiar from the earlier
6 preparation, but as far as what his role was, I
7 don't recall exactly.

8 Q Okay. And do you know who the
9 International Society of Regulatory Toxicology and
10 Pharmacology is?

11 A In a very general sense, yes.

12 Q What's -- what's your understanding as
13 to who they are?

14 A Well, our -- certain members of the
15 Science department I know participate in meetings
16 of different professional societies and outside
17 organizations involved in toxicology, and they may
18 have gone to meetings of this group.

19 Q Okay. And are -- are you aware that
20 with the coordination again of Stephen Gettings --
21 who was the director of toxicology at one time,
22 correct?

23 A Yes, sounds right.

24 Q When -- when did he leave?

1 A I think he left in the late '90s.

2 Q Okay. You're aware, are you not, that
3 with the coordination of Dr. Gettings at the IS RTP
4 held meetings looking at, -- as far back as 1994,
5 looking at the association of talc and ovarian
6 cancer?

7 MR. LOCKE: Objection to form and beyond
8 the scope.

9 BY MR. GOLOMB:

10 Q Were you aware of that?

11 A Not specifically.

12 Q Okay. And were you aware that the CTFA
13 contributed \$20,000 towards that, quote/unquote,
14 workshop?

15 A Not -- not specifically.

16 Q So I asked you earlier about the
17 Weinberg Group.

18 A Mm-hmm.

19 Q I assume from your answers you either
20 haven't or don't recall reviewing the Weinberg
21 Group report.

22 A Again, it's so long ago, it's possible I
23 read it at the time. I -- I can't be sure.

24 Q Okay. Well, the report was authored in

1 October of 2000, weeks before the NTP
2 presentation. Does that help refresh your
3 recollection at all?

4 A Not really. I mean...

5 MR. GOLOMB: Exhibit 12.

6 (Pollak Exhibit No. 12 was marked
7 for identification.)

8 BY MR. GOLOMB:

9 Q This is Exhibit 12, and just to put this
10 into context, this is the page that follows --

11 A Right.

12 Q -- Exhibit 11.

13 A Mm-hmm.

14 Q Which I asked you some questions about
15 before, the organization of the CIR.

16 A Mm-hmm.

17 Q And if we go to section 12 on page 5.

18 A Mm-hmm. Right. So -- so there would be
19 one monitor --

20 Q Let me just -- let me ask you a
21 question.

22 Under Section 12, "Director. (a) the
23 director shall be appointed by the chair of the
24 steering committee." Correct?

1 A So as -- so it's the current title is
2 executive director.

3 Q Okay.

4 A And, yes, the executive director is
5 formally appointed by the chair of the steering
6 committee.

7 Q And the -- in this case the director as
8 well as the chair of the steering committee are
9 both PCPC employees.

10 A Yes.

11 Q Okay. And then under (b): "The
12 director" -- again, who is a PCPC employee --
13 "shall hire and direct the activities of the CIR
14 staff."

15 So you've got the executives of the PCPC
16 are directing the activities of the CIR staff --

17 A No, no.

18 Q -- in order to implement these
19 procedures effectively and efficiently, correct?

20 A No.

21 Q Is that not what it says?

22 A No, it's the exec- --

23 Q Did I read that incorrectly?

24 A Remember it's the executive director who

1 is the CIR employee. The executive director of
2 CIR is directing the activities of the CIR staff.

3 Q Okay. Appointed by the chair of the
4 steering committee, which is the PCPC executive.

5 A Yes.

6 Q Okay. So -- and the chairman of the
7 steering committee -- under (b)(2), "The chairman
8 of the steering committee shall periodically
9 review CIR expenditures." Correct?

10 A Yes.

11 Q So -- and these are a number of the
12 expenditures that we talked about before, like
13 salaries, office supplies, office space --

14 A Mm-hmm.

15 Q -- travel to meetings --

16 A Yes.

17 Q -- all of those things that we talked
18 about previously.

19 A Yes.

20 Q They're all directed by the PCPC
21 ultimately, correct?

22 MR. LOCKE: Objection to form.

23 THE WITNESS: At a minimum, reviewed,
24 yes. I mean they have a budget and every

1 department is --

2 BY MR. GOLOMB:

3 Q Right. And the --

4 A -- supposed to keep within their budget.

5 Q And the executives of the PCPC approve
6 that budget and can approve overexpenditures or
7 not at its sole discretion.

8 A Yes.

9 Q And then as we go further down under
10 (a)(3), "All CIR contracts and capital
11 expenditures shall be reviewed and approved by the
12 chairman of the steering committee prior to
13 execution."

14 So when the CIR enters into a contract,
15 like they did with Dr. Josh Muscat or they did
16 with Dr. Alfred Wehner or like they did with
17 Dr. Huncharek, all those contracts have to be
18 approved by the chairman of the steering committee
19 who was an executive at the PCPC, correct?

20 MR. LOCKE: Objection to form.

21 THE WITNESS: Yes, we would have to
22 approve the contracts. I'm not familiar with
23 those specific contracts, though.

24 BY MR. GOLOMB:

1 Q Understood. But if -- if I told you
2 that those are various scientists that were hired
3 for the purposes of defending the -- the PCPC and
4 its interested members, any contract with those
5 people would first have to be approved by the
6 PCPC.

7 MR. LOCKE: Objection. Are you talking
8 about CIR or PCPC?

9 MR. GOLOMB: CIR.

10 THE WITNESS: So, no, that wouldn't be
11 the purpose of the CIR contract.

12 BY MR. GOLOMB:

13 Q Okay. Have you seen the -- the CIR
14 study on the association of talc and ovarian
15 cancer?

16 MR. LOCKE: Objection. Beyond the
17 scope.

18 THE WITNESS: I -- I don't recall.
19 Again, that's possible in preparation for the last
20 deposition I did see it, but I don't know.

21 BY MR. GOLOMB:

22 Q Okay. Do you know one way or the other
23 as to whether or not one exists?

24 A Yeah. No, I know they reviewed it,

1 so...

2 Q And you know that based on everything
3 that we've talked about this morning, based on
4 these two documents, 11 and 12, if there was such
5 a -- if there was such a study, and it was paid
6 for, it would have to be -- it would have to first
7 be approved by the chairman of the steering
8 committee that happens to be an executive with the
9 PCPC, correct?

10 MR. DONATH: Objection.

11 MR. LOCKE: Objection to form.

12 THE WITNESS: Right. But the purpose of
13 the contract would be to develop additional data
14 to meet the request of the expert panel members.
15 It isn't to defend particular ingredients. It's
16 to try to develop more information.

17 BY MR. GOLOMB:

18 Q And -- but this CIR contract would first
19 have to be approved by an executive of the PCPC.

20 A Yes.

21 Q And that executive of the PCPC gets
22 his -- his -- his salary from the operating
23 expenses of the PCPC. Correct?

24 A Yes.

1 Q And the PCPC operating expenses comes
2 from the industry members, like J&J, like Imerys.

3 A Yes.

4 Q Right. And do you know one way or the
5 other as to whether or not before -- after such a
6 contract is entered into and after a report is
7 issued under this contract, whether or not those
8 members who are paying dues to the PCPC, who are
9 then paying for the research that's done by the
10 CIR, whether or not they have an opportunity to
11 review those studies before they get circulated?

12 MR. LOCKE: Objection.

13 MR. DONATH: Objection. Beyond the
14 scope.

15 MR. LOCKE: And to form.

16 THE WITNESS: And they -- and they
17 wouldn't have an opportunity.

18 BY MR. GOLOMB:

19 Q They wouldn't?

20 A No.

21 Q And you know that how?

22 A If the CIR is doing a contract for a
23 study, it would go back to the CIR expert panel
24 members. It wouldn't be going out to the members

1 as part of the process.

2 Q So you would --

3 A If it was -- and if it was being made
4 available publicly, it would be made available to
5 everyone.

6 Q Okay. So you would agree with me that
7 had the -- the CIR before publishing their study
8 on the association between talc and ovarian
9 cancer, if they had circulated a draft report or
10 more than one draft report to its members, like
11 Johnson & Johnson, like Imerys, that that would be
12 an inappropriate thing to do?

13 MR. LOCKE: Objection.

14 MR. DONATH: Objection. This is all
15 beyond the scope of the notice.

16 THE WITNESS: Well --

17 MR. LOCKE: Wait. Objection. Beyond
18 the scope and to form.

19 THE WITNESS: The members are not
20 members of the CIR. It's a separate thing.

21 BY MR. GOLOMB:

22 Q Well, I understand that.

23 But would you agree with me that had the
24 CIR contracted out to do a study, like they did in

1 this case, to look at the association between talc
2 and ovarian cancer -- one of the things that you
3 told me last time and that you told me again today
4 is it is important for the CIR to be independent.
5 Correct?

6 A Yes.

7 MR. LOCKE: Objection. It's compound,
8 assumes facts not in evidence, and incorrect. And
9 beyond the scope.

10 MR. GOLOMB: Anything else you want to
11 object to?

12 MR. LOCKE: Well, your -- the
13 fundamental premise of your whole argument is --

14 MR. GOLOMB: No, no, no, don't --

15 MR. LOCKE: You asked --

16 MR. GOLOMB: No, no.

17 MR. LOCKE: You asked me if there is
18 anything else.

19 MR. GOLOMB: No, no, no. No speaking
20 objections. You made your objection.

21 MR. LOCKE: But you asked me.

22 MR. GOLOMB: No -- no, I didn't really.

23 MR. LOCKE: You said if there was
24 anything else. I'm explaining to you.

1 MR. GOLOMB: Yeah. And I appreciate
2 that.

3 BY MR. GOLOMB:

4 Q You -- you have made a point, as have
5 others, on the last deposition and this deposition
6 that -- that it's important for the CIR to
7 maintain its independence, correct?

8 A Yes.

9 Q Okay. And would you -- you would agree
10 with me, would you not, that in maintaining one's
11 independence, credibility is very important?
12 Would you agree with that?

13 A Yes.

14 Q And would you agree with me that in a
15 case where the CIR has -- is contracting out to,
16 in this case, Dr. Huncharek to write a report,
17 that you lose credibility if you're now -- if he
18 is providing a draft back to not only the PCPC but
19 the members of the Talc Interested Party Task
20 Force.

21 MR. LOCKE: Objection to form --

22 MR. DONATH: Objection to form, beyond
23 the scope of the notice.

24 MR. LOCKE: -- and beyond the scope.

1 BY MR. GOLOMB:

2 Q Would you agree?

3 A I have no knowledge of what really the
4 study did or what the protocols were and who --
5 who it was shared with.

6 Q Well, my -- I'm sorry, to interrupt you.
7 I want to wait and make sure you've answered your
8 question.

9 You would agree with me under my
10 hypothetical, if that was done, you've got a
11 credibility problem.

12 MR. DONATH: Objection.

13 MR. LOCKE: Objection to form and beyond
14 the scope.

15 THE WITNESS: I think it's beyond my
16 area of expertise. I don't know what the normal
17 protocol is in these studies.

18 BY MR. GOLOMB:

19 Q Okay. Well, you were the one before who
20 said that they didn't do that. How do you know
21 that they didn't do that?

22 MR. LOCKE: Objection. Didn't do what?

23 BY MR. GOLOMB:

24 Q Didn't provide the draft reports to not

1 only the PCPC but to -- to members of the
2 interested party task force.

3 MR. LOCKE: Objection to form, beyond
4 the scope.

5 BY MR. GOLOMB:

6 Q You were the one who said it.

7 A I --

8 MR. DONATH: Objection.

9 MR. LOCKE: Again, same objection.

10 THE WITNESS: I -- you know, I don't
11 know -- I would think that that would not be under
12 the procedures the way it would be handled.

13 MR. LOCKE: Can -- can we take a break
14 to see if lunch is here?

15 MR. GOLOMB: Sure. You know, if you
16 want to take a five-minute break before doing
17 that, and don't move, we may not need a break.

18 MR. LOCKE: Okay. Can I just -- can the
19 witness -- can we just take a break so the witness
20 can go out and go to the bathroom and come back,
21 and the rest of us just stay here?

22 MR. GOLOMB: Sure.

23 THE VIDEOGRAPHER: The time is
24 12:12 p.m., and we're going off the record.

1 MR. LOCKE: Let me wait until the
2 witness leaves and then suggest one thing.

3 I don't want to in any way influence
4 what the witness is saying or not. You can ask
5 all your questions. There is no document that
6 indicates CIR ever contracted with Huncharek,
7 Muscat or any other expert.

8 If you've got it, that's great, show it
9 to the witness, but I don't think any of us have
10 seen it, and if you want to confer with your
11 co-counsel, I suspect they will tell you the same
12 thing.

13 MR. GOLOMB: Okay. Anything else?

14 MR. LOCKE: No, I'm just --

15 MR. GOLOMB: Thanks.

16 (Recess.)

17 THE VIDEOGRAPHER: The time is
18 12:32 p.m. We're back on the record.

19 MR. GOLOMB: First of all, I just want
20 to -- I just want to -- I did check with my
21 colleagues, and, Mr. Locke, you're correct, I
22 misstated the author of the CIR report. It's
23 Monice Fiume.

24 BY MR. GOLOMB:

1 Q Is that your understanding?

2 A I have no -- no knowledge of it.

3 Q Okay. I just don't remember, is she
4 still with the --

5 A Yeah, she is.

6 Q Okay. But in any event, if she's the
7 author of the study, you would agree that it would
8 be inappropriate to provide that study to both the
9 PCPC and PCPC members to edit and review for
10 comment before it went and got -- it actually got
11 published?

12 MR. LOCKE: Objection to form and beyond
13 the scope.

14 THE WITNESS: I think there's a
15 possibility that the -- somebody looked at it to
16 make sure it was what the panel was expecting or
17 that the language, you know, was concise and
18 understandable, but I -- I really don't know.

19 BY MR. GOLOMB:

20 Q Okay. Before when we were -- if you
21 remember, I was asking you some questions about
22 the -- the Dezenhall group and --

23 A Yes.

24 Q -- their crisis management work that

1 they were doing at around the time of the NTP, and
2 you had mentioned that -- that the PCPC had
3 retained Dezenhall on a -- on a previous occasion
4 on some fragrance issues.

5 Do you remember what you -- when you
6 told me?

7 A Yes, I do.

8 Q What were you referring to?

9 A Multiple chemical sensitivity. There
10 was a whole campaign against the industry by
11 people who claimed when they were exposed to other
12 people wearing fragrances, they experienced
13 multiple chemical sensitivity.

14 Q And -- and what was Dezenhall's role?

15 A So we worked with them on, I guess,
16 communications materials. I -- I don't recall if
17 there was any research done or how it was more
18 media related.

19 Q Okay. By the way, you had mentioned to
20 us earlier that the -- I had asked you when the
21 next board meeting was of the -- the
22 September 24th board meeting was --

23 A No, that's the CIR expert panel meeting.

24 Q Yeah.

1 A The board meeting is October 3rd.

2 Q Okay. But you told us that the CIR
3 meeting was open to the public.

4 A Correct.

5 Q Right. And you also told us that it
6 would be on the CIR website.

7 A It should be. They post the meeting
8 announcements.

9 Q Okay. We -- we checked the CIR website
10 during the break, and it's not on there. So do
11 you know when it will be posted?

12 MR. LOCKE: Objection. Form.

13 THE WITNESS: I don't.

14 BY MR. GOLOMB:

15 Q Do you know what the agenda is for that
16 meeting?

17 A No.

18 Q Do you know whether or not -- how -- how
19 is the agenda for a CIR meeting like that
20 selected --

21 MR. LOCKE: Object --

22 BY MR. GOLOMB:

23 Q -- and finalized?

24 MR. LOCKE: Objection. Beyond the

1 scope.

2 You can answer.

3 THE WITNESS: I think Linda Loretz is in
4 a better position to -- to discuss that.

5 BY MR. GOLOMB:

6 Q Okay. But you don't know -- sitting
7 here today, you don't know generally what the
8 issues are and specifically whether or not --

9 A Well, I know --

10 Q Let me just finish the question.
11 -- and specifically whether or not the
12 association of talc and ovarian cancer is on that
13 agenda?

14 A I -- the agenda would be the tentative
15 final and final reports that are ready for
16 presentation to the expert panel, and I'm not
17 aware of anything involving talc coming up.

18 Q Okay. Let me just ask you, is -- is
19 Whitaker Clark Daniels, are they a member of the
20 PCPC?

21 A I think so. I mean they have been in
22 the past.

23 Q Brenntag Specialties?

24 A I'm not familiar with them.

1 Q Cyprus Amax?

2 A I -- the -- Cyprus Minerals I'm familiar
3 with. I assume it's the same company.

4 Q Rio Tinto?

5 A I don't know.

6 Q Do you know who Crowell & Moring is?

7 A Yes, a law firm.

8 Q Okay. Are they a member?

9 A I don't think so. We do have a few law
10 firms who are members for marketing purposes.

11 Q What do you mean "for marketing
12 purposes"?

13 A They made a decision to be a sponsor at
14 a legal conference, and to, you know, basically
15 to -- business development, so they joined the
16 association as an associate member.

17 Q Okay. But you don't know one way or the
18 other whether or not Crowell & Moring is one of
19 them?

20 A They may be. I know there are eight to
21 ten law firms who are members, and I -- I'm just
22 not familiar with them, who they all are.

23 Q You have the revenue chart for the task
24 force?

1 A Mm-hmm.

2 Q Yes? You have to --

3 A No. 3 -- Exhibit No. 3?

4 Q Yeah. The -- on that -- on that
5 sheet -- now, my understanding is that that sheet
6 was prepared shortly before your 2016 deposition.
7 And if that's correct, does that mean that there
8 have not been any contributions to the interested
9 party task force since 2009?

10 A I would presume so. That's what it
11 indicates.

12 Q Okay. Well, how can we -- how can we
13 find out for sure whether or not -- I mean I --
14 I'm assuming that also because that document was
15 prepared in 2016, and I would assume, you correct
16 me if I'm wrong, that if contributions were made
17 in 2010, 2011 through 2016, that it would be on
18 that sheet.

19 A I agree.

20 Q Okay. So if we -- if we assume it's
21 true that no funds have been received from the
22 members of the interested party task force since
23 2009, and we know that the CIR report came well
24 after 2009, how was it paid for?

1 A So the -- I think there are two ways
2 that it can be paid for. CIR has some money in
3 their budget for reports or research that are
4 requested by the expert panel members. And,
5 again, I don't know the specifics of this -- of
6 this particular report that you're talking about,
7 and there have been other instances where there --
8 the panel wants more information, and some company
9 agree -- some companies agree to fund it.

10 Q So --

11 A But I -- again, this is just general. I
12 have no idea what applies in this.

13 Q Right. So, hypothetically, it may be
14 the case that not only did member groups have an
15 opportunity to comment and edit on the report but
16 also pay for it?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 THE WITNESS: Possibly. I don't know
20 how this was set up.

21 BY MR. GOLOMB:

22 Q Do you know who the Health Research
23 Group is?

24 A No.

1 Q Do you know who the --

2 A So is --

3 Q -- Consumer Research Group is?

4 A Excuse me. So is this on -- should I
5 look at this list?

6 Q Sure. If that helps.

7 A Yeah. No, they're off.

8 Q Are they on there?

9 A No.

10 Q Do you know who the Consumer Research
11 Group is?

12 A No.

13 MR. GOLOMB: I don't have any further
14 questions.

15 Can I see the --

16 THE WITNESS: Exhibit 4.

17 BY MR. GOLOMB:

18 Q Yeah, this is Exhibit 4 we're looking
19 at, and you've got the -- it says "Consumer
20 Federal," but we agree it's the Consumer
21 Federation --

22 A Right.

23 Q -- of America, right?

24 And they made payments of \$367,000

1 between 2002 and 2018. I guess my question is
2 why?

3 A So I would assume it's for --

4 MR. LOCKE: Let me object to form. I
5 think that shows payments that PCPC made to these
6 other entities.

7 MR. GOLOMB: You're correct.

8 BY MR. GOLOMB:

9 Q Why?

10 A So -- I think there are two -- two
11 areas. Number one, the Consumer Federation of
12 America has an annual fundraising dinner and they
13 feature prominent speakers, and I think for years
14 we've been buying a table at the event. It's
15 probably five or 10,000.

16 Plus the -- the liaison from Consumer
17 Federation of America is entitled -- the liaison
18 to the CIR expert panel is entitled to
19 reimbursement for his or her preparation time, and
20 the time that he or she spends at the expert panel
21 meeting at the same rate the other expert
22 panels -- expert panel members are entitled to
23 reimbursement. And I think in this case they --
24 the individual can't have the check made out to

1 them. They have it made out to Consumer
2 Federation of America.

3 Q You also mentioned earlier in the -- in
4 the deposition, I was asking you about the -- we
5 were talking about this transition from the desire
6 to be self-regulatory to having some mandatory
7 regulation to be consistent internationally,
8 correct?

9 Do you remember that --

10 A Mm-hmm.

11 Q -- those series of questions?

12 A Yes.

13 Q You mentioned in the course of one of
14 your answers that you had hired some outside
15 consumer research groups to help you through that
16 transition. Who did you use?

17 MR. LOCKE: Objection to form and beyond
18 the scope.

19 You can answer.

20 THE WITNESS: Frank Luntz and Michael
21 Maslansky.

22 BY MR. GOLOMB:

23 Q Frank Luntz. And what did you use Frank
24 Luntz to do?

1 MR. LOCKE: Same objection.

2 THE WITNESS: And again, some of this
3 may have been subcontracted. You know, before we
4 changed the name, they did, you know, I guess
5 online surveys, possibly focus groups on how
6 different names -- the, you know, favorability
7 ratings by different brackets of consumers and
8 other stakeholders, and probably on some of the --
9 you know, consumer awareness of different issues
10 in the cosmetic media space.

11 BY MR. GOLOMB:

12 Q And was it based on that research, at
13 least in part, why the name was changed from the
14 CTFA to PCPC?

15 A Partially, yes.

16 Q Okay. And if -- if somebody, you know,
17 at a cocktail party asked you and said, Why did
18 the CTFA change their name to PCPC -- I understand
19 there are some boring cocktail parties in D.C.
20 where they would have such conversations -- what
21 would your answer be, why?

22 A Mainly because the term "toiletry" was
23 archaic, and people didn't really know what it
24 meant anymore, and we had to get away from using

1 that.

2 Q Okay. And did you -- were there any
3 other consumer research groups that you -- outside
4 consumer research groups that you used?

5 A No.

6 Q For any other issues?

7 A There may have been at the time, but
8 I -- I wouldn't have been involved in the name
9 change.

10 MR. GOLOMB: Okay. I don't have
11 anything further, unless my colleagues have
12 something. Michelle always has something.

13 (Counsel conferring.)

14 MR. GOLOMB: We'll only be another hour
15 or so.

16 (Laughter.)

17 MR. GOLOMB: Can I see the
18 organizational chart again?

19 BY MR. GOLOMB:

20 Q First of all, to your knowledge, whether
21 it was Frank Luntz or some other consumer research
22 group, were there any other -- were there any
23 outside consumer research groups that was hired by
24 PCPC to deal with any talc issue that you're aware

1 of?

2 MR. LOCKE: Objection. Beyond the
3 scope.

4 THE WITNESS: So, again, are you
5 referring to the time of the name change or --
6 BY MR. GOLOMB:

7 Q No, at any time. We -- we talked
8 about --

9 A I don't think -- I don't think a public
10 affairs firm -- you know, I know that
11 Nichols-Dezenhall made a pitch, but I don't think
12 we did anything with it. And other than that, I'm
13 not aware of any other firm.

14 Q Okay. So let me just be clear about
15 that, because the -- you used the term "consumer
16 research group" when we were talking much earlier
17 about the name change, and then I talked -- I just
18 asked you about Frank Luntz. At least that was
19 part of your answer.

20 My -- my -- so using your terminology of
21 "consumer research group," do you consider
22 Nichols-Dezenhall a consumer research group?

23 A Not really. I mean Nichols-Dezenhall is
24 much more focused on media relations.

1 Q Right.

2 A What I meant by consume- -- a group that
3 does research on consumer attitudes.

4 Q Okay. And my question to you is, has
5 the PCPC, to your knowledge, hired any such
6 consumer research group to deal with talc issues?

7 MR. LOCKE: Objection. Beyond the
8 scope.

9 THE WITNESS: Again, not that I'm aware
10 of.

11 BY MR. GOLOMB:

12 Q Okay. And my last question is related
13 to Monice -- how do you pronounce her last name?

14 A Fiume.

15 Q Is she still -- on the chart it has her
16 as scientific analyst.

17 A So she got a promotion, and I -- whether
18 it's senior scientific or deputy director,
19 she's -- she's at a higher level than on that
20 organization chart.

21 Q Okay. And have her duties and
22 responsibilities changed or just her title?

23 A So the reason she got the promotion is
24 because she has a fair amount of responsibility of

1 reviewing the draft reports that the other science
2 writers prepare there, as well as doing her own
3 reports.

4 Q And when did her promotion take place?

5 A Last year.

6 Q When last year?

7 A Probably -- approximately a year ago,
8 sometime during the summer, when the previous
9 executive director Lillian Gill retired, and we
10 made the determination to promote Bart, and then
11 we did promote Monice also.

12 Q Okay. And did somebody do a performance
13 review of Monice?

14 A I assume that Bart did.

15 Q Okay. And do you know whether or not
16 her -- her promotion had anything to do with the
17 publication of the CIR report?

18 A Of the specific report or --

19 Q Yeah.

20 A No. I mean, in general, she would --
21 you know, the -- the staff writers have reports
22 that are part of the normal processes. There are
23 different layers of review and editing to make
24 sure the -- the language is accurate and precise.

1 Q Would it -- would a -- a performance
2 evaluation -- the last performance evaluation of
3 an employee before they were promoted tell us
4 anything about the reasons why they were promoted?

5 A Possibly.

6 Q Okay. And so if -- if Monice was
7 promoted because of her involvement in a -- in a
8 CIR report concerning talc and the association
9 with ovarian cancer, would it be reasonable to
10 assume that that may be part of her performance
11 review?

12 A I would be very surprised that one
13 particular report would be cited that way.

14 Q Has there been any additional research,
15 whether it's CIR or retained by somebody that PCPC
16 hired, on the association of talc and ovarian
17 cancer since the CIR report, to your knowledge?

18 MR. LOCKE: Objection. Beyond the
19 scope.

20 THE WITNESS: Not to my knowledge.

21 MR. GOLOMB: Okay. I have no further
22 questions. You should -- you should probably run
23 before somebody starts handing me more notes.

24 MR. LOCKE: Does anyone else have any

1 questions?

2 No questions.

3 THE VIDEOGRAPHER: Okay. The time is
4 12:51 p.m., August 29th, 2018. We are going off
5 the record, completing the videotaped deposition.

6 (Whereupon, the deposition of
7 MARK POLLAK was concluded
8 at 12:51 p.m.)

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2 The undersigned Certified Shorthand Reporter
3 does hereby certify:

4 That the foregoing proceeding was taken before
5 me at the time and place therein set forth, at
6 which time the witness was duly sworn; That the
7 testimony of the witness and all objections made
8 at the time of the examination were recorded
9 stenographically by me and were thereafter
10 transcribed, said transcript being a true and
11 correct copy of my shorthand notes thereof; That
12 the dismantling of the original transcript will
13 void the reporter's certificate.

14 In witness thereof, I have subscribed my name
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7 it.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby
certify that I have read the foregoing pages, and
that the same is a correct transcription of the
answers given by me to the questions therein
propounded, except for the corrections or changes
in form or substance, if any, noted in the
attached Errata Sheet.

MARK POLLAK DATE

Subscribed and sworn to
before me this
_____ day of _____, 20____.
My commission expires: _____

Notary Public

Exhibit 132

Linda Loretz, Ph.D.

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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

-----x

IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)

-----x

V O L U M E I I I

VIDEOTAPED 30(b)(6) DEPOSITION OF DEFENDANT
PERSONAL CARE PRODUCTS COUNCIL
by and through its Designated Representative,

LINDA LORETZ, Ph.D.

WASHINGTON, D.C.

TUESDAY, OCTOBER 2, 2018

9:01 A.M.

Reported by: Leslie A. Todd

Linda Loretz, Ph.D.

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<p>1 Deposition of LINDA LORETZ, Ph.D., held at the</p> <p>2 offices of:</p> <p>3</p> <p>4</p> <p>5 SEYFARTH SHAW LLP</p> <p>6 975 F Street, N.W.</p> <p>7 Washington, DC 20004</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12 Pursuant to notice, before Leslie Anne Todd,</p> <p>13 Court Reporter and Notary Public in and for the</p> <p>14 District of Columbia, who officiated in</p> <p>15 administering the oath to the witness.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 APPEARANCES (CONTINUED):</p> <p>2</p> <p>3 NICHOLAS J. KOHRS, ESQUIRE</p> <p>4 LUNDY, LUNDY, SOILEAU & SOUTH, LLP</p> <p>5 501 Broad Street</p> <p>6 Lake Charles, Louisiana 70601</p> <p>7 (337) 439-0707</p> <p>8</p> <p>9 ON BEHALF OF PCPC AND THE WITNESS:</p> <p>10 THOMAS T. LOCKE, ESQUIRE</p> <p>11 SEYFARTH SHAW LLP</p> <p>12 975 F Street, NW</p> <p>13 Washington, DC 20004</p> <p>14 (202) 463-2400</p> <p>15</p> <p>16 ON BEHALF OF JOHNSON & JOHNSON DEFENDANTS:</p> <p>17 KATHLEEN FRAZIER, ESQUIRE</p> <p>18 SHOOK, HARDY & BACON, LLP</p> <p>19 600 Travis Street</p> <p>20 Suite 3400</p> <p>21 Houston, Texas 77002-2926</p> <p>22 (713) 227-8008</p> <p>23</p> <p>24</p> <p>25</p>
Page 765	Page 767
<p>1 A P P E A R A N C E S</p> <p>2</p> <p>3 ON BEHALF OF THE PLAINTIFFS:</p> <p>4 TED G. MEADOWS, ESQUIRE</p> <p>5 P. LEIGH O'DELL, ESQUIRE</p> <p>6 RYAN BEATTIE, ESQUIRE</p> <p>7 BEASLEY, ALLEN, CROW, METHVIN, PORTIS &</p> <p>8 MILES, P.C.</p> <p>9 218 Commerce Street</p> <p>10 Montgomery, Alabama 36104</p> <p>11 (334) 269-2343</p> <p>12</p> <p>13 RICHARD M. GOLOMB, ESQUIRE</p> <p>14 BENJAMIN ISSER, ESQUIRE</p> <p>15 GOLOMB & HONIK, P.C.</p> <p>16 1835 Market Street, Suite 2900</p> <p>17 Philadelphia, Pennsylvania 19103</p> <p>18 (215) 985-9177</p> <p>19</p> <p>20 MICHELLE A. PARFITT, ESQUIRE</p> <p>21 ASHCRAFT & GEREL, LLP</p> <p>22 4900 Seminary Road, Suite 650</p> <p>23 Alexandria, Virginia 22311</p> <p>24 (703) 997-1774</p> <p>25</p>	<p>1 APPEARANCES (CONTINUED):</p> <p>2</p> <p>3 ON BEHALF OF THE IMERYS DEFENDANTS:</p> <p>4 JONATHAN F. DONATH, ESQUIRE</p> <p>5 COUGHLIN DUFFY, LLP</p> <p>6 350 Mount Kemble Avenue</p> <p>7 Morristown, New Jersey 07962</p> <p>8 (973) 267-0058</p> <p>9</p> <p>10 CATHERINE SLAVIN, ESQUIRE</p> <p>11 GORDON & REES SCULLY MANSUKHANI, LLP</p> <p>12 Three Logan Square</p> <p>13 1717 Arch Street, Suite 610</p> <p>14 Philadelphia, Pennsylvania 19103</p> <p>15 (215) 717-4006</p> <p>16</p> <p>17 ON BEHALF OF PTI:</p> <p>18 JAMES W. MIZGALA, ESQUIRE</p> <p>19 TUCKER ELLIS, LLP</p> <p>20 233 South Wacker Drive</p> <p>21 Suite 6950</p> <p>22 Chicago, Illinois 60606-9997</p> <p>23 (312) 624-6307</p> <p>24</p> <p>25</p>

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Linda Loretz, Ph.D.

<p style="text-align: right;">Page 768</p> <p>1 APPEARANCES (CONTINUED):</p> <p>2</p> <p>3 ALSO PRESENT:</p> <p>4</p> <p>5 KATIE TUCKER (Paralegal - Beasley Allen)</p> <p>6 EMILY H. MANOSO, Staff Counsel, PCPC</p> <p>7 THOMAS F. MYERS, Staff Counsel, PCPC</p> <p>8</p> <p>9 DANIEL HOLMSTOCK (Videographer)</p> <p>10 JONATHAN VADERS (Technical Support)</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 770</p> <p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>4 No. 91 Draft: FDA-PCPC Telecon 110409,</p> <p>5 November 4, 2009, Bates</p> <p>6 PCPC_MDL00044971 to 000044973 917</p> <p>7 No. 92 Minutes of Safety and Regulatory</p> <p>8 Toxicology Committee, Bates</p> <p>9 PCPC_MDL00006526 to 00006535 924</p> <p>10 No. 93 PCPC Council Executive Committee</p> <p>11 Meeting Agenda, June 6, 2013,</p> <p>12 Bates PCPC_MDL00000875 to 00000882 932</p> <p>13 No. 94 Memorandum re Comments on the</p> <p>14 Scientific Literature Review on</p> <p>15 Talc, October 15, 2012, Bates</p> <p>16 PCPC_MDL00002908 to 00002911 940</p> <p>17 No. 95 E-mail string re CIR final draft,</p> <p>18 Bates Pltf_IMERYYS_00017841 to</p> <p>19 00017842 943</p> <p>20 No. 96 PCPC Detailed Trial Balance sheets</p> <p>21 General Ledger, Bates PCPC_MDL</p> <p>22 00145273 to 00145325 956</p> <p>23 No. 97 PCPC Detailed Trial Balance sheets</p> <p>24 General Ledger, Bates PCPC_MDL</p> <p>25 00145326 to 00145358 958</p>
<p style="text-align: right;">Page 769</p> <p>1 CONTENTS</p> <p>2 EXAMINATION OF LINDA LORETZ, Ph.D. PAGE</p> <p>3 By Mr. Meadows 774</p> <p>4 By Mr. Golomb 1067</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9 EXHIBITS</p> <p>10 (Attached to transcript)</p> <p>11 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>12 No. 86 Cosmetic Ingredient Review Procedures</p> <p>13 Bates IMERYYS 118788 to 118814 811</p> <p>14 No. 87 Personal Care Products Council,</p> <p>15 Public Affairs Issues, Messaging</p> <p>16 Guide 2008, Bates PCPC00117629 to</p> <p>17 0017705 860</p> <p>18 No. 88 CIR 2012 Annual Report 883</p> <p>19 No. 89 CIR Assessing the Safety of Cosmetic</p> <p>20 Ingredients: Recent Case Studies,</p> <p>21 Bates PCPC_MDL00020026 891</p> <p>22 No. 90 Minutes of Safety and Regulatory</p> <p>23 Toxicology Committee, Bates</p> <p>24 PCPC0082732 to 0082742 908</p> <p>25</p>	<p style="text-align: right;">Page 771</p> <p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>4 No. 98 Talc Refs, Bates PCPC0067797 to</p> <p>5 0067799 974</p> <p>6 No. 99 Talc Refs, Bates PCPC_MDL00022149</p> <p>7 to 00022158 980</p> <p>8 No. 100 Memorandum re 125th Meeting of the</p> <p>9 CIR Expert Panel - Monday and</p> <p>10 Tuesday, December 10-11, 2012,</p> <p>11 Bates PCPC_MDL00127808 to 00127826 982</p> <p>12 No. 101 CIR Expert Panel Expense Report,</p> <p>13 Bates PCPC_MDL00145272 987</p> <p>14 No. 102 Memo re Upcoming CIR review of</p> <p>15 talc and CRE submission of relevant</p> <p>16 information, Bates PCPC_MDL00023425 988</p> <p>17 No. 103 E-mail string re talc, Bates</p> <p>18 PCPC0004567 to 0004571 995</p> <p>19 No. 104 125th Cosmetic Ingredient Review</p> <p>20 Expert Panel Meeting, December 10-11,</p> <p>21 2012, Bates PCPC_MDL00103539 to</p> <p>22 00103546 1008</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>4 No. 105 Green, Safety Assessment of Talc</p> <p>5 as Used in Cosmetics, CIR Expert</p> <p>6 Panel Meeting, December 10-11,</p> <p>7 2012, Bates PCPC0028634 to</p> <p>8 0028973 1015</p> <p>9 No. 106 125th Cosmetic Ingredient Review</p> <p>10 Expert Panel Meeting, Main Session,</p> <p>11 December 10, 2012, Bates</p> <p>12 PCPC0011582 to 0011834 1020</p> <p>13 No. 107 125th Cosmetic Ingredient Review</p> <p>14 Expert Panel Meeting, Breakout</p> <p>15 Session December 10, 2012, Bates</p> <p>16 PCPC0011431 to 0011581 1027</p> <p>17 No. 108 125th Cosmetic Ingredient Review</p> <p>18 Expert Panel Meeting, December 11,</p> <p>19 2012, Bates PCPC0011835 to 0011909 1034</p> <p>20 No. 109 Scientific Literature Review, Talc</p> <p>21 as Used in Cosmetics, Bates IMERYS</p> <p>22 029459 to 029544 1041</p> <p>23 No. 110 Article entitled "Safety Assessment</p> <p>24 of Talc as Used in Cosmetics" 1043</p> <p>25</p>	<p>1 PROCEEDINGS</p> <p>2 -----</p> <p>3 THE VIDEOGRAPHER: The time is 9:01 a.m.</p> <p>4 on October 2nd, 2018. We are on the record with</p> <p>5 video 1 of Volume III in the continued deposition</p> <p>6 of Dr. Linda Loretz.</p> <p>7 CROSS-EXAMINATION</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q Good morning, Dr. Loretz.</p> <p>10 A Good morning.</p> <p>11 Q It's been several weeks since I was last</p> <p>12 able to question you. So just as a reminder, my</p> <p>13 name is Ted Meadows, and I represent women who</p> <p>14 have filed lawsuits and claimed to have been</p> <p>15 injured as a result of using baby powder and</p> <p>16 Shower to Shower resulting in ovarian cancer.</p> <p>17 You understand that, right?</p> <p>18 A Yes.</p> <p>19 Q And I called you Dr. Loretz, and if you</p> <p>20 will just remind us the reason why it's</p> <p>21 appropriate to call you doctor.</p> <p>22 A I have a Ph.D.</p> <p>23 Q In?</p> <p>24 A In toxicology.</p> <p>25 Q And you, as we talked about before, are</p>
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<p>1 EXHIBITS</p> <p>2 (Attached to transcript)</p> <p>3 LORETZ DEPOSITION EXHIBITS PAGE</p> <p>4 No. 111 The Rose Sheet, Bates JNJ 000637879</p> <p>5 to 000637881 1048</p> <p>6 No. 112 Letter to Samuel Epstein from</p> <p>7 Department of Health and Human</p> <p>8 Services, April 1, 2014 1064</p> <p>9 No. 113 Executive Committee Meeting,</p> <p>10 January 25, 2001, Hair Dyes,</p> <p>11 Bates PCPC0055865 to 0055869 1086</p> <p>12 No. 114 Document dated January 19, 2009,</p> <p>13 Policy Area: Cosmetics</p> <p>14 Regulation, Bates JNJTALC000494340</p> <p>15 to 000494349 1104</p> <p>16 No. 115 Letter to F. Alan Andersen from</p> <p>17 EUROTALC, October 19, 2012,</p> <p>18 Bates IMERYS 033243 to 033255</p> <p>19 and 033251 1119</p> <p>20 No. 116 Letter to Ian Phillipson from</p> <p>21 CTFA, June 6, 1996, Bates</p> <p>22 PCPC0072694 to 0072695 1124</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 here to testify as a representative and on behalf</p> <p>2 of PCPC, correct?</p> <p>3 A That's correct.</p> <p>4 Q And what is your -- if you will remind</p> <p>5 us one more time, what is your role at PCPC? What</p> <p>6 is your job title and your role?</p> <p>7 A My title is director of Safety and</p> <p>8 Regulatory Toxicology. And I am, as I say, a</p> <p>9 toxicologist. I work within the Science</p> <p>10 department. I report to the executive</p> <p>11 vice president of Science at PCPC. And I -- well,</p> <p>12 I'm a toxicologist. So...</p> <p>13 Q Okay. All right. And so by education</p> <p>14 and training, you are a toxicologist, correct?</p> <p>15 A Yes.</p> <p>16 Q Okay. You might recall last time I was</p> <p>17 here to -- to ask you some questions, we talked</p> <p>18 about a few toxicology principles. Do you</p> <p>19 remember that?</p> <p>20 A Yes.</p> <p>21 Q Okay. And I have a few more that I've</p> <p>22 picked up along the way that I think are correct,</p> <p>23 but I'd like to talk to you about them and see if</p> <p>24 you agree with me. Is that okay?</p> <p>25 A Sure.</p>

4 (Pages 772 to 775)

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<p>1 Q Okay. So I've got a little sheet here.</p> <p>2 We'll kind of just take these one at a time. That</p> <p>3 might be the easiest way to do it.</p> <p>4 All right. So the first one I have</p> <p>5 here -- bear with me as I relearn how to use this</p> <p>6 thing.</p> <p>7 All right. So the first one I have</p> <p>8 written here says: "Chronic inflammation is a</p> <p>9 known risk factor for cancer."</p> <p>10 Do you agree with that?</p> <p>11 MR. LOCKE: Objection. Beyond the</p> <p>12 scope, calls for expert testimony.</p> <p>13 THE WITNESS: I guess I would not call</p> <p>14 myself an expert in cancer risk assessment</p> <p>15 factors. I -- I think there are situations where</p> <p>16 that is true, but I would not -- I mean, I</p> <p>17 would -- I would defer that to people with greater</p> <p>18 expertise than I have.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Okay. So to that you say you're not a</p> <p>21 cancer, I think you said, risk factor expert; is</p> <p>22 that correct?</p> <p>23 A That's a very general, broad statement,</p> <p>24 and I guess I would -- for me to comment on that,</p> <p>25 I -- there are others with greater expertise on</p>	<p>1 You would defer to others with greater</p> <p>2 expertise.</p> <p>3 A Again, I think that's a -- it's a very</p> <p>4 broad statement.</p> <p>5 Q But you would defer to others with</p> <p>6 greater expertise.</p> <p>7 A A broad statement that I know has truth</p> <p>8 in it, but I'm -- again, I'm just not a -- I don't</p> <p>9 believe I'm testifying as an expert in cancer risk</p> <p>10 assessment factors.</p> <p>11 Q All right. So the second, what I</p> <p>12 understand to be, toxicology principle would be:</p> <p>13 "Immune cells and inflammatory cells,"</p> <p>14 parentheses, "these are cells such as macrophages,</p> <p>15 leucocytes, white blood cells, eosinophils" -- if</p> <p>16 I'm pronouncing that correctly -- "neutrophils, et</p> <p>17 cetera, are found in tumor tissue."</p> <p>18 MR. LOCKE: Objection. Beyond the</p> <p>19 scope.</p> <p>20 THE WITNESS: Again, that's a very</p> <p>21 broad -- I mean, does the immune system play a</p> <p>22 role in cancer? Absolutely. Are found in tumor</p> <p>23 tissue? Do you mean all tumor tissue? Do you</p> <p>24 mean specific?</p> <p>25 It's too broad of a question to -- for</p>
Page 777	Page 779
<p>1 that than me.</p> <p>2 Q Okay. And are there others at PCPC who</p> <p>3 are greater at that than you?</p> <p>4 A No.</p> <p>5 Q Okay. You're the most knowledgeable</p> <p>6 when it comes to that particular issue at PCPC?</p> <p>7 A I think chronic inflammation is a known</p> <p>8 risk factor for cancer, but I think it's just a</p> <p>9 much more -- I mean, I think there's situational,</p> <p>10 there's -- it's just much more complex than a</p> <p>11 yes/no answer, I guess is what I'm trying to get</p> <p>12 at.</p> <p>13 Q But my question is, are you the most</p> <p>14 knowledgeable person at PCPC with respect to</p> <p>15 cancer risk factor -- risk factors?</p> <p>16 A I'm one of two toxicologists. So yes.</p> <p>17 Q But you do not consider yourself to be</p> <p>18 expert in that field?</p> <p>19 A I mean, I'm a generalist as a</p> <p>20 toxicologist. Again, if we were putting together</p> <p>21 a paper on role of inflammation in cancer, I would</p> <p>22 go to a -- someone who has specific expertise in</p> <p>23 that. So I'm reluctant to expound more than what</p> <p>24 I know.</p> <p>25 Q Okay. Fair enough.</p>	<p>1 me to want to give you a "yes" or "no."</p> <p>2 But certainly immune system plays a role</p> <p>3 in cancer, if you're asking that.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q Too broad, is that what you say?</p> <p>6 A I think it -- yes.</p> <p>7 Q Is there a word or two that you might</p> <p>8 change in this to make it narrow enough that you</p> <p>9 can agree to it?</p> <p>10 A Does the immune system have a role in --</p> <p>11 in cancer? Yes, I -- I mean, I guess I'm not --</p> <p>12 are found in tumor tissue, you mean when --</p> <p>13 it's -- I'm not sure what you're asking here.</p> <p>14 Q Okay. Is it that this too deals with a</p> <p>15 cancer issue, and you would defer to someone with</p> <p>16 greater expertise?</p> <p>17 A The role of the immune system in cancer</p> <p>18 is not something I have specific expertise about.</p> <p>19 Q Okay. Is there anyone at PCPC who has</p> <p>20 greater expertise in that regard than you?</p> <p>21 A No.</p> <p>22 Q "Number 3. The presence of inflammation</p> <p>23 in a tissue can impact all stages of the process</p> <p>24 of forming a tumor."</p> <p>25 MR. LOCKE: Objection.</p>

5 (Pages 776 to 779)

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<p>1 MR. DONATH: Beyond the scope.</p> <p>2 MR. LOCKE: Objection. Beyond the</p> <p>3 scope.</p> <p>4 THE WITNESS: Inflammation can influence</p> <p>5 tumor formation. All stages, I actually don't</p> <p>6 know if that's true.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q Okay. You would defer to someone with</p> <p>9 greater expertise in that regard?</p> <p>10 A Yeah, I think that it needs to be more</p> <p>11 focused, but yes. I mean --</p> <p>12 Q Okay. And is there anyone at PCPC with</p> <p>13 any greater expertise than you that might be able</p> <p>14 to address this?</p> <p>15 A I would say in general, that's why we go</p> <p>16 out to experts at times.</p> <p>17 Q Okay. And when you say "we," who are</p> <p>18 you talking about?</p> <p>19 A PCPC.</p> <p>20 Q Okay. And when you say you go out to</p> <p>21 experts, give me an example of what you're</p> <p>22 referring to.</p> <p>23 A An example, when it's an epidemiology</p> <p>24 question, we go out to epidemiologists. Just as</p> <p>25 an example.</p>	<p>1 Q Now, when it comes to --</p> <p>2 A I mean, we could. There could be an</p> <p>3 issue that -- but I can't think of an example</p> <p>4 where we have. I'm not -- yeah.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q When it comes to women's reproductive</p> <p>7 system issues, does PCPC reach out to experts in</p> <p>8 that regard?</p> <p>9 A It would depend on what the issue is.</p> <p>10 We reach out to experts when -- when the situation</p> <p>11 calls for it. I can't think of a time when we've</p> <p>12 reached out to an expert on women's reproductive</p> <p>13 system issues, and I'm not sure what quite is</p> <p>14 meant by that, but...</p> <p>15 Q Okay. Well, for instance, one of the</p> <p>16 issues, as I understand it, that PCPC and CIR have</p> <p>17 had with respect to whether baby powder or talc</p> <p>18 can cause ovarian cancer is whether the talc can</p> <p>19 migrate to the ovaries.</p> <p>20 Did I say that correctly?</p> <p>21 A Yes.</p> <p>22 Q So at any point in time, has PCPC or the</p> <p>23 CIR, for that matter, reached out to an expert</p> <p>24 specializing in women's reproductive system</p> <p>25 issues?</p>
Page 781	Page 783
<p>1 Q Okay. So following that line, when it</p> <p>2 comes to epidemiology, is it fair to say that PCPC</p> <p>3 seeks opinions from epidemiologists, right?</p> <p>4 A We do.</p> <p>5 Q When it comes to cancer issues, does</p> <p>6 PCPC seek those with expertise in cancer?</p> <p>7 A I'm trying to think of what an example</p> <p>8 would be.</p> <p>9 Q Well, why don't we use ovarian cancer as</p> <p>10 an example. Does PCPC reach out to experts in</p> <p>11 ovarian cancer at any point in time?</p> <p>12 A I think we evaluate the epidemiology</p> <p>13 studies, and we have reached out to</p> <p>14 epidemiologists.</p> <p>15 Q Okay. The question is, has PCPC reached</p> <p>16 out to cancer experts when it comes to ovarian</p> <p>17 cancer?</p> <p>18 A I can't think of a specific -- where</p> <p>19 we've reached out to an ovarian cancer expert.</p> <p>20 Q Okay.</p> <p>21 MR. LOCKE: Just for clarity, you are</p> <p>22 not asking in the context of litigation, are you?</p> <p>23 MR. MEADOWS: I'm asking in the context</p> <p>24 of the way PCPC carries on their daily activities.</p> <p>25 BY MR. MEADOWS:</p>	<p>1 MR. LOCKE: Objection to form, and asked</p> <p>2 and answered.</p> <p>3 THE WITNESS: PCPC, CTFA at the time,</p> <p>4 conducted a study to look at that issue, and</p> <p>5 there's various ways to look at that issue.</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q Okay. And --</p> <p>8 A We conducted the study that was</p> <p>9 considered to be the best way we could answer that</p> <p>10 question.</p> <p>11 Q Okay. And which study are you referring</p> <p>12 to?</p> <p>13 A I'm referring to the monkey study.</p> <p>14 Q The monkey study. Did the monkey study</p> <p>15 have a name?</p> <p>16 A The Battelle study conducted at</p> <p>17 Battelle. That would have been in the early '80s.</p> <p>18 Q Okay. And do you consider that to be</p> <p>19 the definitive study on whether talc can migrate</p> <p>20 to the ovaries?</p> <p>21 A I think it's one of -- of many lines of</p> <p>22 evidence.</p> <p>23 Q Okay. So there's lots of studies out</p> <p>24 there that address this issue; is that right?</p> <p>25 A And it's a very difficult issue to</p>

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<p>1 address to get a good answer in a women's</p> <p>2 reproductive system.</p> <p>3 Q Well, beyond the study, has PCPC or CIR</p> <p>4 ever sought the opinion of -- of an expert in the</p> <p>5 field of reproductive system issues when it comes</p> <p>6 to ovarian cancer?</p> <p>7 MR. LOCKE: Objection to the extent that</p> <p>8 it relates to this litigation and experts retained</p> <p>9 in connection with this litigation.</p> <p>10 THE WITNESS: I mean, I -- I know for</p> <p>11 example, people from PC -- or CTFA met with</p> <p>12 Dr. Heller, and that would have been before my</p> <p>13 time, but about -- but I'm not even sure what her</p> <p>14 position is right off the top of my head. But...</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q When was that meeting?</p> <p>17 A Well, that was in our review of</p> <p>18 documents. I guess that was in the '80s.</p> <p>19 Q What was the context of that meeting?</p> <p>20 A I think she was one who published or was</p> <p>21 doing work on talc and ovaries, and we were</p> <p>22 genuinely trying to understand, you know, is this</p> <p>23 a real thing? I mean, that was our response to</p> <p>24 the study in '82, the Cramer study, is, you know,</p> <p>25 there's a real question about how does talc</p>	<p>1 A That's not what I would say about</p> <p>2 myself, no.</p> <p>3 Q Okay. And so who is the toxicologist</p> <p>4 you're referring to that served on the CIR panel?</p> <p>5 A Well, Curt Klaassen.</p> <p>6 Q Okay.</p> <p>7 A And -- and, I mean, it was written --</p> <p>8 the report was written by a toxicologist. Ivan</p> <p>9 Boyer, as I understand, had the --</p> <p>10 THE REPORTER: What was the --</p> <p>11 THE WITNESS: Ivan Boyer.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Klaassen and Boyer. Have you ever known</p> <p>14 them to hold themselves out to be experts in</p> <p>15 women's reproductive system issues?</p> <p>16 A No.</p> <p>17 Q Anybody else that served on the CIR</p> <p>18 panel that made the decision that might have an</p> <p>19 expertise in women's reproductive system issues?</p> <p>20 A Not -- not as a specific expertise, no.</p> <p>21 Q How about as a nonspecific expertise?</p> <p>22 A I mean, my answer is no. No, they're</p> <p>23 not --</p> <p>24 Q Okay. Now, going back to the Heller</p> <p>25 meeting, who else attended that Heller meeting?</p>
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<p>1 migrate, and we were trying to address that.</p> <p>2 That's when the monkey study came out.</p> <p>3 Q Tell me what you learned from the Heller</p> <p>4 meeting.</p> <p>5 A I think her results in the end were</p> <p>6 inconclusive. But, again, we were just trying to</p> <p>7 understand what was going on. So did we seek</p> <p>8 experts, I mean, I think we did.</p> <p>9 Q Okay. And in the course of the CIR</p> <p>10 evaluating talc and ovarian cancer, did the CIR</p> <p>11 consult with any experts in the field of women's</p> <p>12 reproductive system issues?</p> <p>13 A I mean, I suppose I can't really say.</p> <p>14 I'm not aware. You know, I'm not aware that they</p> <p>15 did.</p> <p>16 Q Was there anyone who served on the panel</p> <p>17 that made the decision that had an expertise in</p> <p>18 women's reproductive system issues?</p> <p>19 A Certainly not as a primary expertise.</p> <p>20 Q How about as a secondary expertise?</p> <p>21 A Well, I mean, there's a toxicologist.</p> <p>22 So...</p> <p>23 Q Okay. Do you, as a toxicologist,</p> <p>24 consider yourself to be an expert when it comes to</p> <p>25 women's reproductive system issues?</p>	<p>1 A You know, I don't know. I -- I reviewed</p> <p>2 it, and, again, this was certainly years before I</p> <p>3 was there, and I -- I know a meeting was held, and</p> <p>4 I -- I don't know.</p> <p>5 Q Do you know of this meeting because you</p> <p>6 saw documents to that effect?</p> <p>7 A Yes.</p> <p>8 Q Okay. Are there any documents that you</p> <p>9 can look at that you have available to you that</p> <p>10 would refresh your recollection in that regard?</p> <p>11 A Well, I'm sure there are. I -- again,</p> <p>12 it's -- I -- I don't know. I mean --</p> <p>13 Q Would you like to go look at some of</p> <p>14 your documents to see if you can refresh your</p> <p>15 recollection in that regard?</p> <p>16 A Well, what's the question?</p> <p>17 Q Who attended the Heller meeting?</p> <p>18 A Oh. I can't answer that. I mean, is</p> <p>19 that -- I would have to look at documents.</p> <p>20 Q And that's my question, do you want to</p> <p>21 go look at documents so we can discuss this?</p> <p>22 A I guess I would ask my attorney.</p> <p>23 MR. LOCKE: Well, if you have a document</p> <p>24 you want to show her, that's fine.</p> <p>25 MR. MEADOWS: I don't. I don't know</p>

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<p>1 what document she's talking about. So she is the</p> <p>2 one that said she looked at documents that were</p> <p>3 at -- that brought this to her attention, so I'm</p> <p>4 asking her if she wants to go look at her</p> <p>5 documents to see if she can refresh her</p> <p>6 recollection on this so that we can discuss it</p> <p>7 now. If not, then maybe we discuss it on a later</p> <p>8 day.</p> <p>9 MR. LOCKE: Well, what I would say is</p> <p>10 why don't we move on to other topics, and then</p> <p>11 I'll consider whether she should look at documents</p> <p>12 now, and we can talk about it. They were</p> <p>13 documents that have been produced.</p> <p>14 MR. MEADOWS: All right, I'll move on.</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q Okay. Next principle --</p> <p>17 MR. LOCKE: I'm sure if you had one of</p> <p>18 your many colleagues here who could look it up</p> <p>19 online, you will see many documents with Heller's</p> <p>20 name on it.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q All right. Next principle that I have</p> <p>23 here is kind of a long one. And if you have</p> <p>24 trouble seeing this, just let me know, and I'll</p> <p>25 pass this across to you.</p>	<p>1 MR. LOCKE: Beyond the --</p> <p>2 MR. DONATH: Objection. Beyond the</p> <p>3 scope.</p> <p>4 MR. LOCKE: Same objection.</p> <p>5 THE WITNESS: As a toxicologist, I agree</p> <p>6 with those, yes.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q Okay. Next one. "Talc is in foods and</p> <p>9 drugs and we are exposed to it every day," period.</p> <p>10 Do you agree with that?</p> <p>11 A I don't know if we are exposed to it</p> <p>12 every day from foods and drugs.</p> <p>13 Q Oh, okay.</p> <p>14 "But we know that talc ingested orally</p> <p>15 does not produce significant amount -- significant</p> <p>16 toxicity in animals, but when talc is put into</p> <p>17 direct contact with tissue," parentheses, "think</p> <p>18 talc glove powder," close parentheses, "it cannot</p> <p>19 be removed from the body, and the tissue reacts by</p> <p>20 initiating an immune system reaction that can lead</p> <p>21 to significant tissue toxicity."</p> <p>22 Do you agree with that?</p> <p>23 MR. LOCKE: Objection. Beyond the scope</p> <p>24 and form.</p> <p>25 THE WITNESS: I -- I don't know. I</p>
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<p>1 I will read it aloud as best I can, and</p> <p>2 then you just let me if you need -- if you want to</p> <p>3 hold this and look at it, I'm glad to hand it to</p> <p>4 you.</p> <p>5 A I can read it.</p> <p>6 Q Okay. All right. So this principle</p> <p>7 says: "In addition to dose, other factors may</p> <p>8 influence the toxicity of the compound."</p> <p>9 Do you agree with that so far?</p> <p>10 A Yes.</p> <p>11 Q Okay. "These include the route of</p> <p>12 entry," parentheses, "oral, inhalation, skin</p> <p>13 contact, et cetera; how you were exposed," close</p> <p>14 parentheses, "duration and frequency of exposure,"</p> <p>15 parentheses, "how long and how often you're</p> <p>16 exposed, differences that are due to variation</p> <p>17 between species," parentheses, "interspecies</p> <p>18 variability, humans and rats may not respond in</p> <p>19 the same way," close parentheses, "and differences</p> <p>20 among members of the same species," parentheses,</p> <p>21 "interspecies -- intraspecies variability, healthy</p> <p>22 adults versus elderly versus children versus</p> <p>23 someone with an underlying health condition, et</p> <p>24 cetera," close parentheses.</p> <p>25 Do you agree with that?</p>	<p>1 mean, if you say put into direct contact with</p> <p>2 tissue, so if it's on my skin, it cannot be</p> <p>3 removed. I think it can be.</p> <p>4 I think if you're talking about</p> <p>5 internally, can -- can the body initiate an immune</p> <p>6 reaction to talc? I believe that's correct. Can</p> <p>7 it form granulomas, I know that's something that's</p> <p>8 known.</p> <p>9 So I think I don't agree with</p> <p>10 everything. Again, it's to put in direct contact</p> <p>11 with tissue, I mean, your skin is a tissue.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Okay. Fair enough.</p> <p>14 And I -- and what I'm hearing, and this</p> <p>15 is my layman ear, so you correct me if I'm hearing</p> <p>16 this incorrectly, okay?</p> <p>17 What I'm hearing is that you take issue</p> <p>18 with this particular statement to the extent that</p> <p>19 we're talking about talc exposure to external</p> <p>20 skin.</p> <p>21 MR. LOCKE: Objection. Form and beyond</p> <p>22 the scope.</p> <p>23 THE WITNESS: I mean, what -- what I'll</p> <p>24 just agree to is that, yes, talc can initiate an</p> <p>25 immune system reaction. It can form granulomas.</p>

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<p>1 That's a known fact. So...</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Okay. And especially when it's exposed</p> <p>4 to some layer of tissue below the skin.</p> <p>5 MR. LOCKE: Objection. Form and beyond</p> <p>6 the scope.</p> <p>7 THE WITNESS: Yeah, I mean, I -- I'm not</p> <p>8 answering all tissues below the skin. I'm just</p> <p>9 saying, taken literally, it sounds like it's --</p> <p>10 you put it on your skin, you can't remove it, and</p> <p>11 that I would, you know, just in a common sense</p> <p>12 way, disagree with.</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q Okay. Well, let me take it a step</p> <p>15 further into the heart of the matter. Do you</p> <p>16 believe that talc can cause this type of reaction</p> <p>17 when exposed to the ovary?</p> <p>18 MR. LOCKE: Objection. Form and beyond</p> <p>19 the scope.</p> <p>20 THE WITNESS: I mean, I know there's</p> <p>21 been some work done. And I know one of the</p> <p>22 arguments against talc causing ovarian cancer is</p> <p>23 that you don't see granulomas, which is a reaction</p> <p>24 that we know you can get from talc.</p> <p>25 BY MR. MEADOWS:</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. Well, given this type of</p> <p>3 principle, do you agree that it's possible that if</p> <p>4 talc does come in contact with the ovary, that it</p> <p>5 can lead to a reaction that can result in cancer?</p> <p>6 MR. DONATH: Objection.</p> <p>7 MR. LOCKE: Objection. You know, we're</p> <p>8 getting to the point where I think I'm going to</p> <p>9 instruct the witness not to answer. She's not</p> <p>10 here as an expert. She hasn't been prepared as an</p> <p>11 expert. She said she's not an expert on cancer.</p> <p>12 She just can't answer these kinds of questions.</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q Let me try it this way.</p> <p>15 MR. MEADOWS: And for the record, I</p> <p>16 disagree with you, Counsel. I do think that she</p> <p>17 is -- this is the appropriate line of inquiry for</p> <p>18 this witness given her expertise, especially in</p> <p>19 her role as a toxicologist working for the PCPC.</p> <p>20 It's -- frankly, it's my duty to explore what her</p> <p>21 knowledge is and what her opinions are.</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q But let me ask you the question this</p> <p>24 way: Does PCPC believe that when the ovary is</p> <p>25 exposed to talc, it can result in a reaction that</p>
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<p>1 Q Okay. So what's your opinion on this as</p> <p>2 a toxicologist?</p> <p>3 MR. LOCKE: Objection. Form and beyond</p> <p>4 the scope.</p> <p>5 THE WITNESS: My opinion on what?</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q On whether talc can cause this type of</p> <p>8 reaction and lead to ovarian cancer.</p> <p>9 MR. LOCKE: Same objection.</p> <p>10 THE WITNESS: I'm -- I'm not aware that</p> <p>11 there's evidence that that's the case.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q You're saying that there is no evidence</p> <p>14 whatsoever that when talc is exposed -- when the</p> <p>15 ovary is exposed to talc, it can lead to a</p> <p>16 reaction that can lead to cancer.</p> <p>17 MR. LOCKE: Objection. Form and beyond</p> <p>18 the scope.</p> <p>19 THE WITNESS: I -- I don't like to</p> <p>20 answer things with no evidence whatsoever. I</p> <p>21 mean, I think you have to look at -- as I</p> <p>22 understand it, there's no -- I mean talc is known</p> <p>23 that it can induce granulomas, and those aren't</p> <p>24 seen, and -- and this is just much more</p> <p>25 complicated than that.</p>	<p>1 can lead to cancer?</p> <p>2 MR. LOCKE: Objection. Form and beyond</p> <p>3 the scope.</p> <p>4 You can try to answer.</p> <p>5 THE WITNESS: I mean the PCPC position</p> <p>6 is that we do not believe that talcum powder</p> <p>7 applied in the perineal area leads to ovarian</p> <p>8 cancer. We have never specifically tried to</p> <p>9 address the question of -- and I'm not saying</p> <p>10 that's -- it's not an answer of a "yes." I'm just</p> <p>11 saying we've never specifically answered the</p> <p>12 question.</p> <p>13 If you can imagine somehow talc being</p> <p>14 exposed to the ovaries in ways that it's not,</p> <p>15 could it possibly lead to -- I mean, we've never</p> <p>16 tried to answer that question because that's not</p> <p>17 the question that's relevant. We're talking about</p> <p>18 the use of talcum powder as a cosmetic.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Okay. So now you said something there</p> <p>21 that leads me to believe that you don't -- or the</p> <p>22 PCPC does not believe that talc reaches the ovary.</p> <p>23 Is that what the issue is?</p> <p>24 A It's one of the issues.</p> <p>25 MR. LOCKE: Objection.</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. So my question is, assuming talc</p> <p>3 does reach the ovary, does PCPC believe that it</p> <p>4 can cause a reaction that can lead to cancer?</p> <p>5 MR. LOCKE: Objection. Scope and form.</p> <p>6 THE WITNESS: And it kind of goes back</p> <p>7 actually to what you said before about duration</p> <p>8 and contact and et cetera. But again, I'm not</p> <p>9 saying "yes" under any circumstances. I'm saying</p> <p>10 based on use of talcum powder as a cosmetic, do we</p> <p>11 believe it can, and the answer's no.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Explain that to me, why -- why -- why</p> <p>14 that particular principle would not apply to the</p> <p>15 ovary if it might apply to other tissue. Why --</p> <p>16 why would it not apply to the ovary?</p> <p>17 MR. DONATH: Objection.</p> <p>18 MR. LOCKE: Objection. Form and beyond</p> <p>19 the scope.</p> <p>20 THE WITNESS: What principle are you</p> <p>21 speaking of?</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q The fact that when talc touches tissue</p> <p>24 underneath the skin, it can result in cancer.</p> <p>25 MR. LOCKE: Objection. Form, beyond the</p>	<p>1 that objection.</p> <p>2 MR. MEADOWS: The deposition notice</p> <p>3 specifically says that issues that I can explore</p> <p>4 or that we can explore as plaintiffs are PCPC's</p> <p>5 knowledge regarding the risk of ovarian cancer</p> <p>6 caused by application of talcum powder products,</p> <p>7 talc and any constituents to the female perineal</p> <p>8 area.</p> <p>9 So I believe that that specifically is</p> <p>10 why, among other reasons, but that specifically is</p> <p>11 why I'm entitled to ask these questions and get</p> <p>12 answers on it.</p> <p>13 MR. LOCKE: Right. And the keyword</p> <p>14 there is "PCPC's knowledge." You're asking for</p> <p>15 expert opinions. What this witness is here for is</p> <p>16 she is a fact witness. You're asking</p> <p>17 hypotheticals not presented by this case.</p> <p>18 So, that's the reason why. She's not</p> <p>19 here as an expert witness. She's here as a fact</p> <p>20 witness about PCPC's knowledge.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q So I'm back to my question.</p> <p>23 Is PCPC of the opinion that when talc is</p> <p>24 in contact with the ovary, it can result in a</p> <p>25 reaction that can lead to cancer?</p>
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<p>1 scope.</p> <p>2 THE WITNESS: Yeah, I mean, I didn't say</p> <p>3 that.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q Okay. So let's clear this up here.</p> <p>6 A I mean, talc is used in pleurodesis.</p> <p>7 It's applied in the chest cavity. The situation</p> <p>8 where we know talc resulted in tumors in rats was</p> <p>9 an overload of the lungs, which is a nonspecific</p> <p>10 reaction. I -- I never said when talc touches</p> <p>11 underneath the skin, it can cause cancer.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Okay. Let me make sure we're clear on</p> <p>14 this, and I'm going to move on, if I can get a</p> <p>15 simple answer out of you.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Does PCPC believe that when talc -- or</p> <p>19 when the ovary is exposed to talc, it's possible</p> <p>20 that it can lead to a reaction resulting in</p> <p>21 cancer?</p> <p>22 MR. LOCKE: Objection. Form, beyond the</p> <p>23 scope, asked and answered.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q Before you answer, let me respond to</p>	<p>1 MR. LOCKE: Objection. Form, beyond the</p> <p>2 scope. You're asking for her opinion or PCPC's</p> <p>3 opinion. PCPC is not a fact -- or is here as a</p> <p>4 fact witness, not for expert opinion.</p> <p>5 And asked and answered.</p> <p>6 You can answer it if you've got</p> <p>7 something different to say than what you</p> <p>8 previously said.</p> <p>9 THE WITNESS: I'm going to say I don't</p> <p>10 believe that is known, but the question again is,</p> <p>11 is what we talk about as talc used as a cosmetic,</p> <p>12 and we do not believe there is evidence for that,</p> <p>13 no.</p> <p>14 But -- but, no, I don't -- I mean, I --</p> <p>15 when I think of talc as a carcinogen, the only</p> <p>16 example I can think of is the -- in the case of</p> <p>17 overload to the lung, and that's a nonspecific --</p> <p>18 it's a nonspecific reaction.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q So it's PCPC's position that talc is not</p> <p>21 carcinogenic, period?</p> <p>22 MR. LOCKE: Objection. Form, beyond the</p> <p>23 scope.</p> <p>24 You can answer.</p> <p>25 THE WITNESS: It's PCPC's opinion that</p>

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<p>1 talc when used as a cosmetic is not carcinogenic.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Well, when talc is not used as a</p> <p>4 cosmetic, can it be carcinogenic?</p> <p>5 MR. LOCKE: Objection. Beyond the</p> <p>6 scope, form, asked and answered.</p> <p>7 If you've got a different answer, you</p> <p>8 can answer it.</p> <p>9 THE WITNESS: I don't have a different</p> <p>10 answer.</p> <p>11 BY MR. MEADOWS:</p> <p>12 Q A different answer than what? I haven't</p> <p>13 asked you that question before.</p> <p>14 MR. LOCKE: You're asking the same</p> <p>15 question with slightly different wording every</p> <p>16 time. If you can explain the difference, please</p> <p>17 do.</p> <p>18 MR. MEADOWS: Well, the difference is</p> <p>19 that she distinguished between cosmetic talc and I</p> <p>20 assume some other type of talc.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q So my question is, setting aside</p> <p>23 cosmetic use of talc, can talc cause ovarian</p> <p>24 cancer?</p> <p>25 MR. LOCKE: And that is calling for an</p>	<p>1 instruction.</p> <p>2 Q Okay. All right. Next principle.</p> <p>3 Now, let me ask you this, you said</p> <p>4 your -- your title is what now with PCPC?</p> <p>5 A Director of Safety and Regulatory</p> <p>6 Toxicology.</p> <p>7 Q Director of Safety and Regulatory</p> <p>8 Toxicology. Okay.</p> <p>9 All right. The next principle I have:</p> <p>10 "There is a difference between hazard and risk</p> <p>11 when you talk about toxicology in the context of</p> <p>12 human health risk assessment."</p> <p>13 Do you agree with that so far?</p> <p>14 A I do.</p> <p>15 MR. LOCKE: Objection. Beyond the</p> <p>16 scope, form.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q "A hazard is anything that can cause</p> <p>19 harm, whereas risk is the potential for hazard to</p> <p>20 cause harm."</p> <p>21 Do you agree with that?</p> <p>22 MR. LOCKE: Objection. Beyond the</p> <p>23 scope, form.</p> <p>24 THE WITNESS: I'm not sure if I would</p> <p>25 word it exactly like that, but I agree with the</p>
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<p>1 expert opinion. The deposition notice was about</p> <p>2 PCPC's knowledge as a fact witness. So it's</p> <p>3 beyond the scope.</p> <p>4 THE WITNESS: And at this point, I don't</p> <p>5 even know if you are talking about industrial talc</p> <p>6 or -- I mean --</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q You tell me. Is there any type of</p> <p>9 talc --</p> <p>10 A And that's what I'm trying to answer.</p> <p>11 Q -- any version of talc that PCPC</p> <p>12 believes is carcinogenic?</p> <p>13 MR. LOCKE: Objection. Beyond the</p> <p>14 scope. We're here to talk about talc as defined</p> <p>15 in your notice, cosmetic talc; not industrial</p> <p>16 grade talc.</p> <p>17 Don't answer that question.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Are you going to --</p> <p>20 MR. LOCKE: And I'm instructing you not</p> <p>21 to answer.</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q Are you going to follow counsel's</p> <p>24 instruction and not answer my question?</p> <p>25 A I'm going to follow counsel's</p>	<p>1 general principle.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q "You can also think of it this way: A</p> <p>4 hazard will not pose any risk to you unless you're</p> <p>5 exposed to enough of that hazard to cause harm.</p> <p>6 Risk associated with hazards can be eliminated or</p> <p>7 at least greatly reduced by reducing exposure."</p> <p>8 Do you agree with that?</p> <p>9 MR. LOCKE: Objection. Form, beyond the</p> <p>10 scope.</p> <p>11 THE WITNESS: That's a general</p> <p>12 toxicology principle, yes.</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q Okay. And the word "hazard" is an</p> <p>15 important word when it comes to regulatory issues</p> <p>16 too, right?</p> <p>17 MR. LOCKE: Objection. Beyond the</p> <p>18 scope, form.</p> <p>19 THE WITNESS: I mean the word "hazard"</p> <p>20 is an important concept in toxicology.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q Okay. Well, in particular, with respect</p> <p>23 to regulatory issues surrounding cosmetics, right?</p> <p>24 A I'm not sure what you mean.</p> <p>25 Q Well, the word "hazard" is important in</p>

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<p>1 the context of the CIR review, right?</p> <p>2 MR. LOCKE: Objection. Form.</p> <p>3 THE WITNESS: Hazard and risk are both</p> <p>4 important.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q In the context of the CIR review.</p> <p>7 A In the context of toxicology in general.</p> <p>8 Q So my question --</p> <p>9 A So general safety assessment.</p> <p>10 Q My question was with respect to the CIR</p> <p>11 review. Is the word "hazard" important in that</p> <p>12 regard?</p> <p>13 A Hazard is a part of the safety</p> <p>14 assessment, so yes.</p> <p>15 Q Okay. And "hazard" is a word that's</p> <p>16 important when it comes to complying with the</p> <p>17 regulations surrounding cosmetics, correct?</p> <p>18 MR. LOCKE: Objection. Form, beyond the</p> <p>19 scope.</p> <p>20 THE WITNESS: I guess I'm really not</p> <p>21 sure what you're meaning. I mean, hazard leads</p> <p>22 to -- when you're doing a safety assessment, first</p> <p>23 you look at hazard, and then you factor in</p> <p>24 exposure, and that gets you to risk. So they're</p> <p>25 all important.</p>	<p>1 I mean, they could have done a comparison --</p> <p>2 sometimes we do exposures that way, and that you</p> <p>3 might compare in different settings, but not that</p> <p>4 I'm aware of.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q My question was simply, would it be</p> <p>7 important to know an answer to that question?</p> <p>8 A Not necessarily.</p> <p>9 Q Okay. Next question. Has PCPC,</p> <p>10 Johnson & Johnson or Imerys studied or</p> <p>11 commissioned a study to determine whether nickel</p> <p>12 increases the risk of ovarian cancer?</p> <p>13 MS. FRAZIER: Object to form.</p> <p>14 THE WITNESS: Well, I mean, I wouldn't</p> <p>15 be aware of a study of what J&J or Imerys would</p> <p>16 have done, but I'm not aware of that, no.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Okay. And how about chromium, cobalt or</p> <p>19 fibrous talc?</p> <p>20 MS. FRAZIER: Object to form.</p> <p>21 THE WITNESS: Not that I'm aware of.</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q Okay. Do you think it would be</p> <p>24 important to know answers to those questions?</p> <p>25 MR. LOCKE: Objection to form.</p>
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<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. We'll get to that a little bit</p> <p>3 later.</p> <p>4 All right. A couple more questions I</p> <p>5 have before we get into the -- into some documents</p> <p>6 here.</p> <p>7 Did PCPC conduct a study to compare the</p> <p>8 amount of actual exposure between cosmetic use of</p> <p>9 talc and exposure in an industrial setting?</p> <p>10 A I don't believe so.</p> <p>11 Q Okay. Do you know if J&J or Imerys ever</p> <p>12 did?</p> <p>13 A Not that I'm recalling.</p> <p>14 Q Do you think that's an important thing</p> <p>15 to know?</p> <p>16 A Say it again.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Did PCPC, Johnson & Johnson or Imerys</p> <p>20 conduct a study to compare the amount of actual</p> <p>21 exposure between cosmetic use of talc and exposure</p> <p>22 in an industrial setting?</p> <p>23 MR. LOCKE: Objection. Asked and</p> <p>24 answered.</p> <p>25 THE WITNESS: Not that I'm aware, but --</p>	<p>1 THE WITNESS: If it were identified as</p> <p>2 a -- as a -- as an issue, yes, but not otherwise.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q Okay. Has PCPC, Johnson & Johnson or</p> <p>5 Imerys studied or commissioned a study to</p> <p>6 determine if the perineal use of talc could result</p> <p>7 in talc reaching the upper genital tract?</p> <p>8 MS. FRAZIER: Object to form.</p> <p>9 THE WITNESS: Can you say that one more</p> <p>10 time?</p> <p>11 BY MR. MEADOWS:</p> <p>12 Q Has PCPC, Johnson & Johnson or Imerys</p> <p>13 studied or commissioned a study to determine if</p> <p>14 perineal use of talc can result in talc reaching</p> <p>15 the upper genital tract?</p> <p>16 MS. FRAZIER: Object to form.</p> <p>17 THE WITNESS: I think the monkey study</p> <p>18 was designed to specifically address that issue.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Okay. Any others?</p> <p>21 A Probably commissioned a study, I would</p> <p>22 say that was -- I think that was the only one.</p> <p>23 Q Okay. And how about the ovaries or the</p> <p>24 fallopian tubes?</p> <p>25 A Well, that was -- the monkey study was</p>

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<p>1 designed to --</p> <p>2 Q Okay.</p> <p>3 A -- to look at that.</p> <p>4 Q And that's the only one that you're</p> <p>5 aware of?</p> <p>6 A That's the only one I can think of, yes.</p> <p>7 Q Okay.</p> <p>8 A That's the only one I'm aware of.</p> <p>9 Again, I can only speak for PCPC.</p> <p>10 Q Okay. Has PCPC, Johnson & Johnson or</p> <p>11 Imerys studied what percentage of the talc applied</p> <p>12 could reach the upper genital tract, ovaries or</p> <p>13 fallopian tubes?</p> <p>14 MS. FRAZIER: Object to form.</p> <p>15 THE WITNESS: I mean, again, I'm not</p> <p>16 sure how you would study that. I think the money</p> <p>17 study -- and I'm not trying to say the monkey</p> <p>18 study like that's all the data that's out there,</p> <p>19 but that was what was done to try to answer that</p> <p>20 question of translocation.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q Okay. But mine has to do with</p> <p>23 percentage of talc that reaches it. Do you --</p> <p>24 have you -- are you aware of any such studies that</p> <p>25 have ever been done?</p>	<p>1 looking at other information that's out there.</p> <p>2 But to try to answer your question.</p> <p>3 Q Okay. Are you aware that there are</p> <p>4 studies showing that exposure to asbestos causes</p> <p>5 ovarian cancer?</p> <p>6 MR. LOCKE: Objection. Form and beyond</p> <p>7 the scope.</p> <p>8 THE WITNESS: I'm aware that IARC has</p> <p>9 said that.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Do you have an opinion as to whether or</p> <p>12 not IARC is correct?</p> <p>13 MR. LOCKE: Objection. Form and beyond</p> <p>14 the scope.</p> <p>15 THE WITNESS: I would not put myself out</p> <p>16 there as an expert on asbestos causing ovarian</p> <p>17 cancer.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Is there anyone at PCPC who would have</p> <p>20 greater expertise than you in that regard?</p> <p>21 A No, and I'm not saying that's incorrect.</p> <p>22 I'm just saying, if you want me to opine on the</p> <p>23 IARC opinion, I couldn't, but I know that they</p> <p>24 have said that.</p> <p>25 Q All right. I want to switch gears now,</p>
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<p>1 MR. LOCKE: Well, are you asking whether</p> <p>2 PCPC has commissioned a study or awareness of</p> <p>3 studies in general?</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q Has PCPC, Johnson & Johnson or Imerys</p> <p>6 studied what percentage of the talc applied could</p> <p>7 reach the upper genital tract, ovaries or</p> <p>8 fallopian tubes?</p> <p>9 MR. LOCKE: Objection to form and scope</p> <p>10 to the extent it relates to Imerys and Johnson &</p> <p>11 Johnson.</p> <p>12 MS. FRAZIER: Join.</p> <p>13 THE WITNESS: And I -- I would just go</p> <p>14 back to -- and I -- I -- the reason I keep talking</p> <p>15 about the monkey study is I think that was -- that</p> <p>16 was what was the study that was commissioned to</p> <p>17 try to get at that question, in general,</p> <p>18 translocation, which would at least theoretically</p> <p>19 kind of get at some idea of percent.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q Okay. So you're saying that the monkey</p> <p>22 study does address how much gets there.</p> <p>23 A Well, because they didn't find any</p> <p>24 getting there, then that's zero percent. I'm not</p> <p>25 saying there's not another -- that it's not worth</p>	<p>1 and -- I'm gong to need a document here -- but I</p> <p>2 want to switch gears now to the Cosmetic</p> <p>3 Ingredient Review, and try to gain a little better</p> <p>4 understanding as to what the CIR is.</p> <p>5 And my attempt at doing that is going to</p> <p>6 be with the help of Plaintiffs' Exhibit 86.</p> <p>7 (Exhibit No. 86 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q All right. So, Dr. Loretz, I've handed</p> <p>11 you what I've marked as Plaintiffs' 86. Do you</p> <p>12 recognize that document?</p> <p>13 A In various -- with different dates, but</p> <p>14 yes.</p> <p>15 Q Okay. And you're referring, I guess, to</p> <p>16 the date there in the middle, October of 2010?</p> <p>17 A Yes.</p> <p>18 Q Okay. I take it there have been some</p> <p>19 different versions of this over the years?</p> <p>20 A I think there's some minor updates</p> <p>21 occasionally.</p> <p>22 Q Okay. I picked October 2010 because</p> <p>23 I -- I'm assuming that was the one that was</p> <p>24 effective -- my best guess was that was the one</p> <p>25 that was in effect at the time of the talc review</p>

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<p>1 in 2012. Is that fair enough to assume?</p> <p>2 A I think that's fair enough, yeah.</p> <p>3 Q Okay. All right. So as we can see,</p> <p>4 it's the Cosmetic Ingredient Review procedures.</p> <p>5 A Yes.</p> <p>6 Q And it's a -- it's got the CIR address</p> <p>7 down here, Washington, D.C., right?</p> <p>8 A Yes.</p> <p>9 Q And then -- and then I tell you what,</p> <p>10 just generally, can you just kind of tell us what</p> <p>11 this document is -- tell the jury what this</p> <p>12 document is, and then I want to dive in into a</p> <p>13 couple of different sections of it.</p> <p>14 A Okay. As you can tell from the table --</p> <p>15 there's a table of contents, and that kind of</p> <p>16 spells out how the Cosmetic Ingredient Review</p> <p>17 works, who is on the panel, or what their roles</p> <p>18 and responsibilities are, how you submit to the</p> <p>19 panel, how their review process works, public</p> <p>20 disclosure. It's basically everything about</p> <p>21 the -- how the panel works, how they conduct their</p> <p>22 business.</p> <p>23 Q Okay. All right. Fair enough. We're</p> <p>24 going -- we're going to cover a couple of things</p> <p>25 in here.</p>	<p>1 Cosmetic Ingredient Review came into being?</p> <p>2 A It came into being in 1976. And I just</p> <p>3 believe that there was a feeling that there should</p> <p>4 be someone out there addressing the safety of</p> <p>5 cosmetic ingredients.</p> <p>6 The FDA, I believe, at the time did not</p> <p>7 feel that they had the resources, and so the</p> <p>8 industry said that -- that we can -- we can do</p> <p>9 that.</p> <p>10 Q All right. Well, there was also some</p> <p>11 responsibility there, right, in the industry?</p> <p>12 MR. LOCKE: Objection to form.</p> <p>13 THE WITNESS: I'm sorry. What's the</p> <p>14 question?</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q Well, there is -- under the regulations,</p> <p>17 there's some responsibility on the part of</p> <p>18 cosmetic -- the cosmetic industry to -- to police</p> <p>19 themselves, right?</p> <p>20 A That is -- that is true.</p> <p>21 MR. LOCKE: Objection to form and scope.</p> <p>22 THE WITNESS: The safe -- the products</p> <p>23 being put on the market need to be safe before you</p> <p>24 can put them on the market.</p> <p>25 BY MR. MEADOWS:</p>
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<p>1 Just --</p> <p>2 (Counsel conferring.)</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q Okay. I'm being told I need to identify</p> <p>5 that this document comes from Imerys Bates No.</p> <p>6 118788, for the record.</p> <p>7 All right. So I'd like to start with,</p> <p>8 Dr. Loretz, going to -- I guess it's page</p> <p>9 numbered 4. And it's the section, Section 2.</p> <p>10 A Yes.</p> <p>11 Q "Purpose of the Cosmetic Ingredient</p> <p>12 Review."</p> <p>13 And it says: "The purpose of the</p> <p>14 Cosmetic Ingredient Review is to determine those</p> <p>15 cosmetic ingredients for which there is a</p> <p>16 reasonable certainty in the judgment of competent</p> <p>17 scientists that the ingredient is safe under its</p> <p>18 conditions of use."</p> <p>19 Did I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q Okay. So the important word there is</p> <p>22 "safe," right?</p> <p>23 A It's one of the important words, yes.</p> <p>24 Q Okay. You know, just as a little bit of</p> <p>25 background, I tell you -- can you tell us how the</p>	<p>1 Q Right. That's what the law is, right?</p> <p>2 A Yes.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q And a company has to be in a position to</p> <p>6 say that their product is safe, right?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Yes.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q All right. And so this was the</p> <p>11 industry's answer to -- to be able to -- for a</p> <p>12 company to be able to say that their product is</p> <p>13 safe, right?</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: It's only one part of it.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q Okay. Well, but this is kind of the</p> <p>18 linchpin of self-regulation, right?</p> <p>19 MR. LOCKE: Objection to form.</p> <p>20 THE WITNESS: I think there's different</p> <p>21 parts of it. I mean, I think there is regulation</p> <p>22 by FDA, no -- no premarket approval. There is --</p> <p>23 but the companies do have a responsibility for</p> <p>24 their products to be safe.</p> <p>25 And certainly as CIR goes through and</p>

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<p>1 reviews ingredients, you know, until they get to</p> <p>2 an ingredient, they haven't done all ingredients.</p> <p>3 So, you know, the industry has responsibility as</p> <p>4 well. So this is one -- one piece of it. One</p> <p>5 important piece of it.</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q Okay. All right. So going back to the</p> <p>8 purpose. Again, the Cosmetic Ingredient Review is</p> <p>9 looking at cosmetic ingredients to determine if</p> <p>10 they're safe, right?</p> <p>11 A Yes.</p> <p>12 Q And there's -- this document lays out</p> <p>13 how that's supposed to be executed correctly?</p> <p>14 A Right, what the procedures are.</p> <p>15 Q Okay. All right. Now, we'll flip back</p> <p>16 over to the first -- or the previous page, if you</p> <p>17 will. It's got -- it's got some definitions in</p> <p>18 here, right?</p> <p>19 A Yes.</p> <p>20 Q Okay. And we saw the word "safe" over</p> <p>21 there under "Purpose." Right?</p> <p>22 A Yes.</p> <p>23 Q So "safe" is defined over here under</p> <p>24 definitions, correct?</p> <p>25 A It is.</p>	<p>1 available information that demonstrates or</p> <p>2 suggests reasonable grounds to suspect a hazard to</p> <p>3 the public under the conditions of use that are</p> <p>4 now current or that might reasonably be expected</p> <p>5 in the future."</p> <p>6 So that's what the CIR is looking for,</p> <p>7 right?</p> <p>8 A That's what it says.</p> <p>9 Q That's the standard by which they are to</p> <p>10 measure an ingredient when they're reviewing it,</p> <p>11 correct?</p> <p>12 A That's what it says.</p> <p>13 Q Okay. And it doesn't say anything about</p> <p>14 cause, right?</p> <p>15 A I think you could question if it's</p> <p>16 implied, but it doesn't say the word there.</p> <p>17 Q The word "cause" is not found in there,</p> <p>18 is it?</p> <p>19 A I mean the word "cause" is not there,</p> <p>20 no.</p> <p>21 Q Correct. And I suspect words are</p> <p>22 important when you're coming up with your</p> <p>23 definitions, right?</p> <p>24 MR. LOCKE: Objection to form.</p> <p>25 THE WITNESS: Words are important.</p>
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<p>1 Q Okay. So under (m): "'Safe' or</p> <p>2 'safety' means no evidence in the available</p> <p>3 information that demonstrates or suggests</p> <p>4 reasonable grounds to suspect a hazard" -- there's</p> <p>5 that word, right?</p> <p>6 A Yes.</p> <p>7 Q -- "to the public under the conditions</p> <p>8 of use that are now current or that might</p> <p>9 reasonably be expected in the future; for example,</p> <p>10 a low incidence of minor adverse reactions as</p> <p>11 shown in the animal or animal testing or product</p> <p>12 experience. Such information includes, but is not</p> <p>13 limited to, the chemical structure of the</p> <p>14 ingredient, published and unpublished tests on the</p> <p>15 ingredient and products containing the ingredient,</p> <p>16 significant human experience on products</p> <p>17 containing the ingredient during marketing, and</p> <p>18 information on similar or related substances. A</p> <p>19 lack of information about an ingredient shall not</p> <p>20 be sufficient to justify a determination of</p> <p>21 safety."</p> <p>22 Correct?</p> <p>23 A That's what it says, yes.</p> <p>24 Q Okay. So going back there, we've got</p> <p>25 "'Safe' or 'safety' means no evidence in the</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Yeah. Instead, the definition of</p> <p>3 "safety" talks about suspecting a hazard, right?</p> <p>4 A That's what it says, yes.</p> <p>5 Q It doesn't say reasonable grounds to</p> <p>6 suspect it causes harm, correct?</p> <p>7 A I think that might be implied, though.</p> <p>8 I mean, it's --</p> <p>9 Q Are there any documents anywhere that</p> <p>10 says that that's the way this is being</p> <p>11 interpreted?</p> <p>12 A I guess I think when they're -- when</p> <p>13 they're looking at ingredients, they're looking at</p> <p>14 causation. I mean, that's just --</p> <p>15 Q Are there any documents anywhere that</p> <p>16 would tell us that this particular definition is</p> <p>17 to be interpreted to imply cause?</p> <p>18 MR. LOCKE: Objection to form.</p> <p>19 THE WITNESS: I guess I'm just wondering</p> <p>20 if you look at CIR reports, if -- if perhaps those</p> <p>21 would suggest that. I mean, there's concern about</p> <p>22 skin irritation, it's -- the implication is, does</p> <p>23 this ingredient cause skin irritation, not -- I</p> <p>24 think maybe that's implied.</p> <p>25 BY MR. MEADOWS:</p>

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<p>1 Q So my question is, are there any</p> <p>2 documents, other than your -- the CIR reports</p> <p>3 themselves, that would say that this definition is</p> <p>4 to be interpreted to mean cause?</p> <p>5 MR. LOCKE: Objection to form, asked and</p> <p>6 answered.</p> <p>7 THE WITNESS: Again, I would just</p> <p>8 suggest that it's implied.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q So you're saying that for the CIR to</p> <p>11 find that a -- an ingredient is not safe, they</p> <p>12 must determine that an ingredient in fact does</p> <p>13 cause a harm.</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: I mean, if something</p> <p>16 doesn't cause a harm, then I'm not sure why you</p> <p>17 would find it unsafe.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Well, it seems to me that this</p> <p>20 definition is saying that suspicion of a hazard is</p> <p>21 enough to say that it's not safe. It doesn't mean</p> <p>22 that to you?</p> <p>23 MR. LOCKE: Objection to form.</p> <p>24 THE WITNESS: Yeah, I think -- I think</p> <p>25 it's very hard to take these words -- I mean, I</p>	<p>1 MR. LOCKE: Can we get Exhibit 71?</p> <p>2 (A discussion was held off the record.)</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q Now, in -- this was Exhibit 71</p> <p>5 yesterday. I think actually it was previously</p> <p>6 marked as 324 in some other setting, but in the</p> <p>7 deposition I think it's been marked as 71.</p> <p>8 And it's from the Code of Federal</p> <p>9 Regulations, Title 21. Right?</p> <p>10 A Yes.</p> <p>11 Q And we're looking at Section 740.1,</p> <p>12 "Establishment of Warning Statements," right?</p> <p>13 A Yes.</p> <p>14 Q And 740.1(a) says: "The label of a</p> <p>15 cosmetic product shall bear a warning statement</p> <p>16 whenever necessary or appropriate to prevent a</p> <p>17 health hazard" -- there's that word again -- "that</p> <p>18 may be associated with the product."</p> <p>19 Did I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q Okay. So there's "hazard" again. And</p> <p>22 this says "may be associated," right?</p> <p>23 A That's what this says.</p> <p>24 Q And the CIR language said "suspect a</p> <p>25 hazard," right?</p>
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<p>1 think you have to look at the reports. I don't</p> <p>2 think suspicion of a hazard, that's not how I read</p> <p>3 this. You're saying because they use the word</p> <p>4 "hazard" instead of "risk"?</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q I didn't say that.</p> <p>7 MR. LOCKE: Is there a question pending?</p> <p>8 MR. MEADOWS: There was.</p> <p>9 MR. LOCKE: I think she answered it.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q So we differ on whether or not cause is</p> <p>12 required in order to -- to find something unsafe</p> <p>13 under the CIR procedures.</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: Again, I don't think it's</p> <p>16 -- specifically the word "cause" isn't addressed</p> <p>17 here. I think -- I think there's a matter of</p> <p>18 interpretation.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q All right. So we've talked about the</p> <p>21 fact that the word "hazard" is important, right?</p> <p>22 A Hazard, risk, exposure, they're all</p> <p>23 important, yes.</p> <p>24 Q Okay. Now, yesterday you were shown</p> <p>25 Exhibit 71. We'll go back --</p>	<p>1 MR. LOCKE: Objection. Form.</p> <p>2 THE WITNESS: That's the words that are</p> <p>3 here.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q Do you see any difference between those?</p> <p>6 MR. LOCKE: Objection to form and beyond</p> <p>7 the scope.</p> <p>8 THE WITNESS: I mean, these are in</p> <p>9 different contexts. I --</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Well, for sure, the word "cause" is not</p> <p>12 used in 740.1, right?</p> <p>13 MR. LOCKE: Objection to form.</p> <p>14 THE WITNESS: The cause -- the word</p> <p>15 "cause" is not in what you're showing me, that's</p> <p>16 correct.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Okay. So much like the CIR standard, we</p> <p>19 don't find that the author of the rule thought it</p> <p>20 important to use the word "cause," right?</p> <p>21 MR. LOCKE: Objection to form.</p> <p>22 THE WITNESS: Yeah, I -- I mean, I think</p> <p>23 it feels like -- I don't know what the author was</p> <p>24 thinking, and again, there gets to be, you know,</p> <p>25 things that are implied. I mean...</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q So you believe it's implied in this rule</p> <p>3 that in order for a cosmetic to be required to</p> <p>4 have a warning on it, that it must be shown to</p> <p>5 cause a particular event.</p> <p>6 MR. LOCKE: Objection to form. And</p> <p>7 beyond the scope.</p> <p>8 THE WITNESS: Yeah, I don't have an</p> <p>9 opinion on that. That's not something -- PCPC</p> <p>10 doesn't do labeling beyond what -- you know, the</p> <p>11 clearcut requirements for labeling. That's what</p> <p>12 our labeling manual does. And so this is not my</p> <p>13 area, nor is it something that we do.</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Okay. So you as director of Safety and</p> <p>16 Regulatory Toxicology, this is not -- 740.1(a) is</p> <p>17 not something that you -- excuse me -- look at or</p> <p>18 use in your role as director of Safety and</p> <p>19 Regulatory Toxicology; is that correct?</p> <p>20 A That's correct.</p> <p>21 Q Okay. Is there anybody at PCPC who</p> <p>22 has -- who uses 740.1(a) on a daily basis, has</p> <p>23 intimate knowledge of it and knows how it's to be</p> <p>24 applied?</p> <p>25 A PCPC doesn't do labeling. So -- I mean,</p>	<p>1 Q -- the word "Council" is used.</p> <p>2 A Okay.</p> <p>3 Q Tell you what, let me mark that one</p> <p>4 here.</p> <p>5 There is a definition there for</p> <p>6 "Council" means the Personal Care Products</p> <p>7 Council, correct?</p> <p>8 A I don't see it, but --</p> <p>9 Q I'm sorry. It's on page 3, the</p> <p>10 definition.</p> <p>11 A Oh, okay, I see it.</p> <p>12 Q It would be letter (j).</p> <p>13 A Yes, I see it now. And, yes, it does</p> <p>14 say that.</p> <p>15 Q So when we see the word "Council"</p> <p>16 throughout this manual, that's what it's referring</p> <p>17 to, correct?</p> <p>18 A Yes.</p> <p>19 Q All right. So flipping over, the</p> <p>20 organization -- let's go to the section that says</p> <p>21 "Organization of the Cosmetic Ingredient Review,"</p> <p>22 Section 10.</p> <p>23 A Okay.</p> <p>24 Q All right. So it talks about: "The</p> <p>25 general policy and direction of the Cosmetic</p>
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<p>1 we do -- again, we have a labeling manual that</p> <p>2 talks about here's what the requirements are, but</p> <p>3 it doesn't get into the area of -- I mean, if a</p> <p>4 company wanted to know if they should label, that</p> <p>5 would not be what we advise on.</p> <p>6 Q Okay. So, again, there's nobody at PCPC</p> <p>7 who would specialize in something -- in anything</p> <p>8 that pertains to 740.1(a)?</p> <p>9 A Correct.</p> <p>10 Q Okay. And are there ever meetings</p> <p>11 amongst your -- your members that are sponsored by</p> <p>12 or that PCPC participates in that pertain to</p> <p>13 discussions as to whether a cosmetic should</p> <p>14 contain a warning under 740.1(a)?</p> <p>15 A I would say no.</p> <p>16 Q Okay. And in particular, with respect</p> <p>17 to cosmetic talc and body powders, has there ever</p> <p>18 been any discussion amongst your members that PCPC</p> <p>19 has been involved in pertaining to whether or not</p> <p>20 a body powder should contain a warning statement?</p> <p>21 A Not that I'm aware of, no.</p> <p>22 Q All right. Going back to 86.</p> <p>23 Throughout the -- this procedures manual, if you</p> <p>24 will --</p> <p>25 A Yes.</p>	<p>1 Ingredient Review shall be given by a steering</p> <p>2 committee." Right?</p> <p>3 A Yes.</p> <p>4 Q And then on down in that paragraph, it</p> <p>5 talks about: "The Steering Committee shall</p> <p>6 consist of the following members." Number 1.</p> <p>7 "The president and CEO of the Council, who shall</p> <p>8 serve as the chair of the Steering Committee."</p> <p>9 Right?</p> <p>10 A Correct.</p> <p>11 Q So "the Council" meaning PCPC, right?</p> <p>12 A Correct.</p> <p>13 Q Okay. Now, number 2, "A dermatologist,</p> <p>14 who shall represent the American Academy of</p> <p>15 Dermatology." Right?</p> <p>16 A Correct.</p> <p>17 Q And 3, "A toxicologist."</p> <p>18 Number 4, "The chair of the Council's</p> <p>19 CIR Science and Support Committee." Right?</p> <p>20 A Correct.</p> <p>21 Q So that's another person from PCPC,</p> <p>22 right?</p> <p>23 A No, actually, that's -- well, I mean,</p> <p>24 it's -- that is a Council committee. The chair</p> <p>25 would be an industry -- a member of the Council.</p>

17 (Pages 824 to 827)

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<p>1 Q Ah, okay. Number 5, "The Council 2 executive vice president for science." 3 And then number 6, "A consumer 4 representative." Right? 5 A Yes. 6 Q I can't remember if there's more here. 7 There's a number 7, and then the "Chair of the CIR 8 expert panel." Right? 9 A Yes. 10 Q Now, what role does this committee play? 11 A They -- they're a steering committee, so 12 they might talk about -- oh, for example, I 13 believe, just to give an example to illustrate, I 14 think when -- when the expert committee was 15 expanded to add two chemists, because that wasn't 16 that long ago, that would be the kind of thing 17 that the -- the steering committee would talk 18 about or discuss. So kind of issues like that. 19 Q Okay. All right. And then we got a 20 Section 11 says: The "Separation and Independence 21 of the CIR staff." Right? 22 A Yes. 23 Q Okay. Now, to make sure we're clear 24 here, I think -- I think some of this has been 25 discussed before, but I just want to make sure I'm</p>	<p>1 A I don't know. Our membership department 2 I think usually would reach out when people 3 discontinue their membership, which -- which 4 happens. People cycle in and out. 5 Q Okay. 6 A But I -- I don't know specifically in 7 this case. 8 Q Have either Imerys or J&J ever cycled 9 out before? 10 A I think as long as I've been there, J&J 11 has been a member. Because I haven't had contact 12 with -- that much contact with Imerys, I couldn't 13 answer that, so I don't know. I'm not aware of 14 it, but I don't know. 15 Q Okay. And is this something that the 16 membership department would want to get to the 17 bottom to -- of and find out why Imerys is no 18 longer a member? 19 A I guess I would just only say that I -- 20 it's an assumption on my part that when someone's 21 a member and then they decline to renew their 22 membership, they're probably contacted by the 23 membership department, in the normal way a 24 business would -- would work. 25 Q But, I guess, as long as you know,</p>
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<p>1 clear on my understanding. 2 The -- the CIR is funded by the PCPC, 3 correct? 4 A That is correct. 5 Q And the PCPC is funded by industry, 6 correct? 7 A Yes. 8 Q So all income for the PCPC comes from 9 companies like Johnson & Johnson and Imerys, 10 correct? 11 A It comes from our members, most of it, 12 and then some -- occasionally we have a small 13 amount of income from outside non-members for 14 meetings, et cetera. But, yes, industry. 15 Q And your -- I'm sorry, your members 16 include Johnson & Johnson and Imerys. 17 A That's correct. Well, actually, Imerys 18 is no longer a member. 19 Q Okay. When -- when did they depart? 20 A I believe this year. 21 Q Okay. Do you have any idea what the 22 circumstances were there? 23 A No knowledge, no. 24 Q No? Any attempt by PCPC to get them 25 back?</p>	<p>1 coming up until this year, Imerys has been a 2 member of PCPC. 3 A As far as I'm aware. 4 Q And as long as you've known or as long 5 as you've been there, Johnson & Johnson has been a 6 member. 7 A That's -- that is true. 8 Q And they continue to be a member. 9 A They are. 10 Q Okay. Back to my question. The funding 11 that comes from industry and members like 12 Johnson & Johnson and Imerys -- 13 A Yes. 14 Q -- funds PCPC, right? 15 A Yes. 16 Q Okay. It pays your salary, right? 17 A Yes. 18 Q Okay. It pays the salary and wages for 19 everyone who works at PCPC, correct? 20 A That's correct. 21 Q It pays the overhead. 22 A Yes. 23 Q And then PCPC then passes some of that 24 money on to CIR to carry on their functions, 25 correct?</p>

18 (Pages 828 to 831)

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<p>1 A Correct, they fund CIR.</p> <p>2 Q Okay. So the same money that industry</p> <p>3 provides to fund PCPC ends up going to CIR to pay</p> <p>4 the salaries and wages of those who work for CIR,</p> <p>5 correct?</p> <p>6 A That's correct.</p> <p>7 Q And the overhead, right?</p> <p>8 A Yes.</p> <p>9 Q Okay. In fact, that -- the last I</p> <p>10 checked, and maybe this has changed, but last I</p> <p>11 checked you actually -- PCPC and CIR share office</p> <p>12 space; is that right? Correct?</p> <p>13 A We are -- we are located -- yes,</p> <p>14 correct.</p> <p>15 Q Okay. There been any discussion of</p> <p>16 maybe moving to different locations?</p> <p>17 A Yeah, at one point they were actually on</p> <p>18 a different floor. They're not now, but -- in</p> <p>19 order to, you know, to seem more independent, but</p> <p>20 I think it's -- we would still be told that, Well,</p> <p>21 they're industry funded, so I think it was</p> <p>22 considered that it wouldn't make that much</p> <p>23 difference.</p> <p>24 Q You share an office space. Do you end</p> <p>25 up sharing supplies?</p>	<p>1 We just talked about that, right?</p> <p>2 A Correct.</p> <p>3 Q Okay. And then it talks about contact</p> <p>4 between the CIR staff and Council staff to be kept</p> <p>5 to a minimum.</p> <p>6 Is that kind of hard to do given you</p> <p>7 share the same office space?</p> <p>8 A I mean, as far as being friendly with,</p> <p>9 of course. I mean, that's kind of normal</p> <p>10 interaction. I think what that really refers to</p> <p>11 is just that you do your job, we do our job, and</p> <p>12 we don't -- we don't interact on our jobs.</p> <p>13 Q And the reason that this separation, if</p> <p>14 you will, exists is for what?</p> <p>15 A Because to keep CIR as independent as</p> <p>16 they can be, but -- but -- I mean, just to say</p> <p>17 this is CIR staff. I mean, the decision makers</p> <p>18 are the expert panel, and there -- there,</p> <p>19 certainly, the independence is more obvious.</p> <p>20 Q "The CIR staff shall follow all the</p> <p>21 personnel policies and procedures established in</p> <p>22 the Council Procedures Manual." Right?</p> <p>23 A Yes.</p> <p>24 Q So not only are they employees, they are</p> <p>25 to abide by the PCPC policies and procedures,</p>
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<p>1 A I think we do share supplies, yes.</p> <p>2 Q Share the same conference rooms?</p> <p>3 A Same what?</p> <p>4 Q Same conference rooms?</p> <p>5 A Yes.</p> <p>6 Q Equipment?</p> <p>7 A Yes.</p> <p>8 Q Okay. So there's a section in here that</p> <p>9 talks about separation and independence of the CIR</p> <p>10 staff, right?</p> <p>11 A Yes.</p> <p>12 Q And in part, it talks about "The CIR</p> <p>13 staff shall be employees of or consultants to</p> <p>14 Council," right?</p> <p>15 A Yes.</p> <p>16 Q So the CIR staff, they're actually</p> <p>17 employees of PCPC.</p> <p>18 A We -- PCPC pays them, that's right.</p> <p>19 Q It goes on to say, "but shall be</p> <p>20 separate and independent from the Council staff."</p> <p>21 Right? And then it goes on, "No person</p> <p>22 on the Cosmetic Ingredient Review staff may also</p> <p>23 serve on the Council staff. The CIR staff may</p> <p>24 obtain supplies and services through the central</p> <p>25 facilities of the Council."</p>	<p>1 correct?</p> <p>2 A Right. Because they're employees, yes.</p> <p>3 Q Now, Section 12, "Director." (a) "The</p> <p>4 director shall be appointed" -- well, first of</p> <p>5 all, who -- tell me what the director is.</p> <p>6 A The head of -- excuse me -- the head of</p> <p>7 CIR staff. So they oversee the report preparation</p> <p>8 basically that goes to the expert panel.</p> <p>9 Q Okay. Now, one -- one person I know to</p> <p>10 have been, I think, the director was Alan</p> <p>11 Andersen, right?</p> <p>12 A Correct.</p> <p>13 Q Okay. He is no longer director?</p> <p>14 A He retired.</p> <p>15 Q Okay. And he retired when?</p> <p>16 A So just roughly -- I don't know, five</p> <p>17 years ago.</p> <p>18 Q Okay. And how long was he the director?</p> <p>19 A A long time. He was director when I</p> <p>20 came in '97, and I'm not sure how long he had been</p> <p>21 at that post. But a long time.</p> <p>22 Q Okay. You're aware he's testified</p> <p>23 before?</p> <p>24 A I think I did know that, yes.</p> <p>25 Q Okay. Have you read his testimony?</p>

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<p>1 A No.</p> <p>2 Q All right. So, "The director shall be</p> <p>3 appointed by the chair of the steering</p> <p>4 committee" --</p> <p>5 Now, which steering committee is that?</p> <p>6 A That's the --</p> <p>7 Q What we were talking about earlier?</p> <p>8 A -- CIR steering committee, correct.</p> <p>9 Q Okay. All right.</p> <p>10 -- "with the approval of the chair of</p> <p>11 the Council Board of Directors and the chair of</p> <p>12 the Council Scientific Advisory Committee."</p> <p>13 So the CIR steering committee appoints a</p> <p>14 director, but it has to be approved by the</p> <p>15 Council -- chair of the Council Board and the</p> <p>16 chair of the Council Scientific Advisory</p> <p>17 Committee, right?</p> <p>18 A That's what it says, yes.</p> <p>19 Q So PCPC has final say over who the</p> <p>20 director is going to be, right?</p> <p>21 MR. LOCKE: Objection to form.</p> <p>22 THE WITNESS: Yeah, there's a lot of</p> <p>23 Council input, yes.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q All right. Going on down. The</p>	<p>1 what he needs, but -- but, yes, ultimately they</p> <p>2 have the -- the budget control.</p> <p>3 Q It goes on to talk about the chairman of</p> <p>4 the steering committee periodically reviewing CIR</p> <p>5 expenditures.</p> <p>6 "All CIR contracts and capital</p> <p>7 expenditures shall be reviewed and approved by the</p> <p>8 Chairman of the Steering Committee."</p> <p>9 And "All CIR office supplies shall be</p> <p>10 obtained through Council central purchasing,</p> <p>11 unless otherwise approved by the Chairman of the</p> <p>12 Steering Committee." Right?</p> <p>13 A Yes.</p> <p>14 Q And that's going back to what we talked</p> <p>15 about earlier, the PCPC pays for the supplies of</p> <p>16 the CIR office.</p> <p>17 A That's correct.</p> <p>18 Q All right. Flipping on over to the next</p> <p>19 page, Section 20, "Members of the Expert Panel and</p> <p>20 Liaison Representatives." (a) "Members of the</p> <p>21 expert panel shall possess the following</p> <p>22 qualifications: (A) Members" --</p> <p>23 And when we say "expert panel," what --</p> <p>24 what are we talking about here?</p> <p>25 A Yeah, so that's -- that's the important</p>
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<p>1 director, he hires and directs the activities of</p> <p>2 the CIR staff. Right?</p> <p>3 A Yes.</p> <p>4 Q "The director shall report to and be</p> <p>5 subject to the direction and control of the</p> <p>6 steering committee with respect to policy and</p> <p>7 budget within the following limitations."</p> <p>8 And that's the steering committee that</p> <p>9 we referred to earlier, right?</p> <p>10 A Yes.</p> <p>11 Q Okay. The limitations that are there</p> <p>12 are that the Council --</p> <p>13 That's the PCPC, right?</p> <p>14 A Yes.</p> <p>15 Q -- board of directors determines the</p> <p>16 budget and personnel limits for the CIR, right?</p> <p>17 A Yes.</p> <p>18 Q So at the end of the day, the PCPC</p> <p>19 decides how much money CIR is going to get, right?</p> <p>20 A That's true.</p> <p>21 Q Not only how much money but how much are</p> <p>22 they going to get in the way of resources and</p> <p>23 personnel, correct?</p> <p>24 A Yeah, I mean, I think the -- the CIR</p> <p>25 director is going to have his opinions and ask for</p>	<p>1 thing to understand about the way -- so far we've</p> <p>2 been talking about CIR staff. Those are the</p> <p>3 people that are housed, and they're -- what they</p> <p>4 do is they put together reports that go to the</p> <p>5 expert panel.</p> <p>6 The expert panel are outside experts. I</p> <p>7 mean, there's a set group of outside experts.</p> <p>8 They meet quarterly. They're from various</p> <p>9 institutions, academic, medical doctors. And so</p> <p>10 that's who the expert panel is. Those are defined</p> <p>11 members with expertise in certain areas,</p> <p>12 toxicology, veterinary and pathology, dermatology,</p> <p>13 chemistry.</p> <p>14 Q Okay. We talked about that a little bit</p> <p>15 earlier, right?</p> <p>16 A Not today, I don't think yet. I</p> <p>17 mentioned it because that's -- yes, they are --</p> <p>18 they are the ones that are truly independent, and</p> <p>19 they're the ones that make the -- the decisions as</p> <p>20 far as --</p> <p>21 Q Okay. But we did talk about the fact</p> <p>22 that -- that those on the panel -- remember</p> <p>23 earlier we were talking about how, particularly on</p> <p>24 the talc panel, there weren't any epidemiologists</p> <p>25 on the panel?</p>

20 (Pages 836 to 839)

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<p>1 A Oh, we talked about that, yes.</p> <p>2 Q And there weren't any experts on female</p> <p>3 reproductive systems, right?</p> <p>4 A Correct.</p> <p>5 Q Okay. All right. So I've also seen</p> <p>6 expert panel sometimes referred to just simply as</p> <p>7 EP. Is that --</p> <p>8 A I've seen it that way. I don't think</p> <p>9 that's real common. I think that was kind of one</p> <p>10 person used to do that, so --</p> <p>11 THE REPORTER: I'm sorry, I couldn't</p> <p>12 hear you.</p> <p>13 THE WITNESS: Oh, I said I think there's</p> <p>14 one person who used to refer to it as EP.</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q All right. So, "Members shall possess</p> <p>17 expertise relevant to the review of the safety of</p> <p>18 cosmetic ingredients."</p> <p>19 Who decides whether or not their</p> <p>20 expertise is relevant to the review of the safety</p> <p>21 of cosmetic ingredients?</p> <p>22 A I think there's -- I mean, it's been --</p> <p>23 for a long time, there's been the makeup of the</p> <p>24 panel with we need dermatologists because of the</p> <p>25 skin. I mean, you could argue there could be</p>	<p>1 A That's his -- that's his area of</p> <p>2 research.</p> <p>3 Q But he's not a -- not a physician.</p> <p>4 A Correct.</p> <p>5 Q Okay. Has he written on cancer issues?</p> <p>6 A Published, yeah.</p> <p>7 Q But you're not familiar with what his</p> <p>8 Ph.D. is in?</p> <p>9 A No.</p> <p>10 Q Okay. All right. So maybe I missed it,</p> <p>11 but I think I asked who determines whether you've</p> <p>12 got the expertise to serve on a particular panel.</p> <p>13 Is there anybody that makes that determination?</p> <p>14 A I -- I mean, I --</p> <p>15 MR. LOCKE: Objection to the extent</p> <p>16 "particular panel" is undefined.</p> <p>17 THE WITNESS: I mean, I think the</p> <p>18 steering committee, but, I mean, it would -- with</p> <p>19 input, and I think there's -- when you talk about</p> <p>20 new expert panel, it means the input is accepted</p> <p>21 from -- from anywhere.</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q Well, let me ask you this: Is -- are</p> <p>24 there different panels for different types of</p> <p>25 cosmetics?</p>
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<p>1 endless expertise that you could bring that, you</p> <p>2 know, might be relevant in certain cases. But</p> <p>3 there's dermatologists, again, there's</p> <p>4 toxicologists, a veterinary pathologist. There's</p> <p>5 more than one dermatologist. There is a cancer</p> <p>6 expert. Maybe I should have said that.</p> <p>7 And then again chemist -- chemist was</p> <p>8 added because it was seen that there was a need</p> <p>9 for more chemistry expertise, and so they added</p> <p>10 two chemists to the panel. I think that was</p> <p>11 roughly in 2009.</p> <p>12 Q Okay. And so who was the cancer expert</p> <p>13 that served on the talc panel?</p> <p>14 A Tom Slaga.</p> <p>15 Q Tom Slaga?</p> <p>16 A Yeah.</p> <p>17 Q Okay. And what's his -- what -- I</p> <p>18 assume your -- he's a medical doctor?</p> <p>19 A No. He's a Ph.D.</p> <p>20 Q Ph.D.?</p> <p>21 A Yeah.</p> <p>22 Q Ph.D. in what?</p> <p>23 A I don't know. I believe he's with the</p> <p>24 University of Texas, I want to say.</p> <p>25 Q What makes him a cancer expert?</p>	<p>1 A No. That's -- there's a standing expert</p> <p>2 panel composition.</p> <p>3 Q For how long?</p> <p>4 A They serve terms, but for -- for long</p> <p>5 periods of time.</p> <p>6 Q And is there a limitation on their</p> <p>7 terms?</p> <p>8 A I -- I think that's spelled out in here,</p> <p>9 but they can be reappointed for one additional</p> <p>10 term, although I -- and then the chair has</p> <p>11 actually been there longer than that. And I'm not</p> <p>12 sure this has been strictly been adhered to, to be</p> <p>13 honest. I think it's -- I think people have</p> <p>14 served longer than two terms.</p> <p>15 Q Okay. I think I see it here. "A member</p> <p>16 shall be appointed to the expert panel for a term</p> <p>17 for six years, and may be reappointed for one</p> <p>18 additional term. These limitations shall apply to</p> <p>19 the chair."</p> <p>20 That's what you're talking about?</p> <p>21 A That's -- yeah.</p> <p>22 Q Okay. So they can serve for as long as</p> <p>23 12 years?</p> <p>24 A Yes. And as I say, I don't think</p> <p>25 that's -- has been strictly adhered to, to be</p>

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<p>1 honest. The limitations do not apply to the</p> <p>2 chair. We've had the same chair for a long time.</p> <p>3 Q Any idea why the number six was chosen</p> <p>4 for those?</p> <p>5 A No idea, no.</p> <p>6 Q All right. So once a panel is picked</p> <p>7 for the year, that's the panel that sits for every</p> <p>8 ingredient that's reviewed in the course of a</p> <p>9 year?</p> <p>10 A Right, right. It's not picked for a</p> <p>11 year. Again, there's a standing panel, and you</p> <p>12 can see that on the CIR website. And, yes, that</p> <p>13 is the standing panel.</p> <p>14 Q Okay. So regardless of what issues</p> <p>15 might come up with an ingredient, the same panel</p> <p>16 sits, right?</p> <p>17 A That's correct.</p> <p>18 Q And makes the decision?</p> <p>19 A Yes.</p> <p>20 Q No matter how complex the issue might</p> <p>21 be, it's going to be the same panel that makes the</p> <p>22 decision, right?</p> <p>23 A Correct.</p> <p>24 Q And if there's a particular issue that</p> <p>25 is complex enough that maybe someone else should</p>	<p>1 veterinary pathology, which is basically to deal</p> <p>2 with the animal studies; that there needs to be</p> <p>3 dermatology expertise; and that's -- that is --</p> <p>4 and chemistry. And that's the makeup of the</p> <p>5 panel.</p> <p>6 Q Now, ultimately the CIR determined that</p> <p>7 talc cannot migrate to the ovaries, correct?</p> <p>8 A I'm not sure what the exact wording was.</p> <p>9 I know they went through that literature.</p> <p>10 Q Okay. And they made that determination</p> <p>11 without any member of the panel having any</p> <p>12 expertise in the female reproductive system,</p> <p>13 correct?</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: I think they made that</p> <p>16 with the data that was before them based on the</p> <p>17 data.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q But there wasn't anybody with any</p> <p>20 sufficient scientific expertise to handle that</p> <p>21 particular issue, was there?</p> <p>22 MR. LOCKE: Objection to form.</p> <p>23 THE WITNESS: I mean, they looked at the</p> <p>24 data that was available. I mean, you're looking</p> <p>25 at -- you know, for example, with the monkey</p>
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<p>1 be involved in the decision-making process,</p> <p>2 that -- there's no provision to allow for someone</p> <p>3 different to come in and sit on that panel.</p> <p>4 A Not to sit --</p> <p>5 MR. LOCKE: Objection to form.</p> <p>6 THE WITNESS: Not to sit on the panel,</p> <p>7 no.</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q Now going back up here. "Members shall</p> <p>10 possess expertise relevant to the review of the</p> <p>11 safety of cosmetic ingredients. They shall have</p> <p>12 diverse professional, education, training, and</p> <p>13 experience so that the expert panel will reflect a</p> <p>14 balanced composition of sufficient scientific</p> <p>15 expertise to handle the issues that come before</p> <p>16 it."</p> <p>17 Did I read that correctly?</p> <p>18 A Yes.</p> <p>19 Q And so how is it determined before a</p> <p>20 panel is chosen that you have a balanced</p> <p>21 composition of sufficient scientific expertise to</p> <p>22 handle the issues that come before it?</p> <p>23 A I guess, as I say, the -- the</p> <p>24 determination was -- was made that there needs to</p> <p>25 be toxicology; that there needs to be vet --</p>	<p>1 study, and I'm not trying to put it out there as</p> <p>2 the end-all, be-all, but, you know, here's the --</p> <p>3 here's what they did. And did it migrate to the</p> <p>4 ovaries, no. I mean...</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q Well, is it -- is it PCPC's belief that</p> <p>7 the panel that made the determination that talc</p> <p>8 does not migrate to the ovaries had sufficient</p> <p>9 scientific expertise to make that determination?</p> <p>10 MR. LOCKE: Objection to form.</p> <p>11 THE WITNESS: I -- I think there's a lot</p> <p>12 of scientific expertise on the CIR expert panel.</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q Well, we've already established that</p> <p>15 there wasn't anybody on that panel that had any</p> <p>16 expertise on the female reproductive system,</p> <p>17 right?</p> <p>18 MR. LOCKE: Objection to form.</p> <p>19 THE WITNESS: I think there's a lot of</p> <p>20 expertise on the CIR expert panel.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q But you'll agree with me there wasn't</p> <p>23 anybody on that panel that had any expertise with</p> <p>24 respect to the female reproductive system,</p> <p>25 correct?</p>

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<p>1 A There wasn't a specific female 2 reproductive specialist on the panel, no, there is 3 not. 4 Q Okay. All right. Slip on over to 5 Section 22. 6 "Selection of liaison representatives to 7 the expert panel. The director shall request that 8 each of the following interests designate a 9 liaison representative to the expert panel." 10 And then it has somebody from the FDA, 11 right? 12 A Correct. 13 Q Somebody from the Consumer Federation of 14 America? 15 A Yes. 16 Q And somebody from PCPC, right? 17 A Correct. 18 Q What does the liaison representative do? 19 A They sit at the table with the expert 20 panel. They can speak. Sometimes they are maybe 21 called on. For example, someone may say, We would 22 like the FDA perspective on this. So they can be 23 used that way, but they can speak and, you know, 24 again, represent -- one representing FDA, one 25 industry, one consumer interest. But they're</p>	<p>1 A Not just the panel, the public too, 2 because it is truly posted on the -- on the 3 website when there's draft reports and the 4 background that goes into them. But, yes, the 5 liaison does. 6 Q Okay. Does the liaison get to speak 7 into the process, express their opinions in the 8 same way that the panel does? 9 A They do. They do at the -- the first 10 day is a meeting, they break into two teams, and 11 they can talk. And then the second -- the second 12 day is really an expert panel discussion, and 13 liaisons are more often called on, but they can 14 speak. 15 Q Okay. And how often -- does the 16 liaison -- well, let's go on down here. Maybe 17 this answers my question. 18 It says there's three people, one 19 representing each of the interests listed. Sorry. 20 Does it tell us how long they serve or 21 are they serving for the same six-year periods? 22 A They're -- I would say they're not 23 serving -- they're -- for the FDA, I mean, it's 24 going to be from the Office of Cosmetics and 25 Colors. It -- it always has. And it's</p>
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<p>1 non-voting. So that's what distinguishes them 2 certainly from the expert panel. 3 Q Okay. So is the liaison representative, 4 with the exception of not being able to vote, do 5 they have the same information and opportunity to 6 speak into the process? 7 A Yeah, I should talk a little bit about 8 how the process is, because it's a very open 9 public process where anybody has the opportunity 10 to speak. So -- 11 Q But my question right now -- 12 A Sure. 13 Q -- is just simply with respect to the 14 liaison, does the liaison get the same information 15 that everybody else on the panel gets, and is the 16 liaison allowed to speak into the process in the 17 same way that everybody else on the panel gets to 18 speak? 19 A Along with the -- 20 MR. LOCKE: Objection. Compound 21 question. 22 BY MR. MEADOWS: 23 Q Okay. Well, let me break it down. Does 24 the liaison get the same information everybody 25 else on the panel gets?</p>	<p>1 actually -- sometimes the director shows up or the 2 head of the office, and sometimes it can be 3 somebody else within the office. 4 Q Okay. 5 A Consumer Federation, I don't think 6 there's limits on anything. I think, for example, 7 that person changed because the previous person 8 left, so then they appointed someone new. 9 And for the Council, it has at least 10 historically been, as long as I've been there, the 11 vice president of Science, and so it changes as 12 the vice president of Science changes. 13 Q Okay. Let me ask it this way: Do 14 the -- the particular -- obviously, this is like 15 a -- it's a person from each of these groups. 16 A Correct. 17 Q So I would assume it may be a different 18 person from -- from meeting to meeting. Is that 19 fair to say? 20 A In general, there is one -- as I say, 21 with the FDA, there's two, three people, and 22 sometimes it -- but it rotates among them. 23 Q Okay. So over the course of a year, if 24 there are multiple meetings of the panel, there 25 may actually be a different person representing</p>

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<p>1 each of these interests at each meeting.</p> <p>2 A Typically, with the exception of FDA,</p> <p>3 there is not, but there could be.</p> <p>4 Q Okay. Consumer Federation of America,</p> <p>5 who are they?</p> <p>6 A They're a non-governmental, a nonprofit.</p> <p>7 Q And any idea why they were chosen to</p> <p>8 have the role?</p> <p>9 A I -- they've been there as long as I've</p> <p>10 been there, so I couldn't tell you what the origin</p> <p>11 is.</p> <p>12 Q Okay. All right. And then PCPC has one</p> <p>13 of the three seats, right?</p> <p>14 A That's correct.</p> <p>15 Q All right. Flipping on over to page 9,</p> <p>16 "Compensation of Expert Panel Members."</p> <p>17 All right. It says: "All members of</p> <p>18 the expert panel and liaison representatives shall</p> <p>19 receive a consultant fee and be reimbursed for</p> <p>20 their travel expenses and all other out-of-pocket</p> <p>21 expenses, unless such compensation and</p> <p>22 reimbursement is waived." Right?</p> <p>23 A Correct.</p> <p>24 Q We already talked about that, that that</p> <p>25 money comes from the PCPC, right?</p>	<p>1 been here, yes.</p> <p>2 Q Okay. And that's actually on page 15.</p> <p>3 A Okay.</p> <p>4 Q And then flipping on over to page 23 at</p> <p>5 the bottom, there's a Section 47, right?</p> <p>6 A Okay.</p> <p>7 Q And it's entitled "Amendment and</p> <p>8 Re-Review of a Final Report."</p> <p>9 What is that section intended for?</p> <p>10 A I guess it would just be what it says.</p> <p>11 Q Okay. Well, Section (a). "Any</p> <p>12 interested person who believes that a Final Report</p> <p>13 is incorrect may petition the Expert Panel to</p> <p>14 amend the Final Report to correct such error."</p> <p>15 Right?</p> <p>16 A Yes.</p> <p>17 Q And down here it says: "A petition to</p> <p>18 amend a Final Report shall ordinarily be based</p> <p>19 upon new data and information not previously</p> <p>20 reviewed by the Expert Panel." Right?</p> <p>21 A Yes.</p> <p>22 Q So is this a process by which the CIR</p> <p>23 can reconvene even after they've issued a final</p> <p>24 decision to reassess what they -- the decision</p> <p>25 that they made on a particular issue?</p>
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<p>1 A Yes.</p> <p>2 Q And then the meetings are held in D.C.,</p> <p>3 right?</p> <p>4 A Correct.</p> <p>5 Q I think that's what it says. Did I mark</p> <p>6 that right?</p> <p>7 An expert panel member -- will be paid</p> <p>8 whether meetings are held in the city of residence</p> <p>9 or elsewhere. Okay.</p> <p>10 And then they can be paid an hourly rate</p> <p>11 when they're working at home, right?</p> <p>12 A Yes.</p> <p>13 Q Or wherever they work, they're paid an</p> <p>14 hourly rate, right?</p> <p>15 A Right.</p> <p>16 Q And then they get a daily rate when</p> <p>17 they're required to travel outside the commuting</p> <p>18 area to perform the assignment, right?</p> <p>19 A That's what it says, yes.</p> <p>20 Q And further over -- I don't know if we</p> <p>21 need to go to it, but I think we just actually</p> <p>22 just said this, all these panning -- expert panel</p> <p>23 meetings are to be held in Washington, D.C.,</p> <p>24 correct?</p> <p>25 A They have always been as long as I've</p>	<p>1 A Yes. And I will say also there's also</p> <p>2 a -- and I'm not sure if it's in here -- but</p> <p>3 there's a -- a routine rereview process as well</p> <p>4 that the panel -- that CIR does where they -- and</p> <p>5 15 years is -- is what they say that at 15 years</p> <p>6 they like to take another look at ingredients that</p> <p>7 have been reviewed, that have final reports, and</p> <p>8 say, Is there new data out here that we should</p> <p>9 look at? And then they will actually go through a</p> <p>10 formal rereview process and decide are we going to</p> <p>11 reopen this and take another look or are we okay</p> <p>12 with it. So...</p> <p>13 Q Okay. So what I think I just heard, and</p> <p>14 just correct me if I'm wrong, as a matter of</p> <p>15 course, an ingredient -- the plan is to have an</p> <p>16 ingredient rereviewed every 15 years.</p> <p>17 A Right.</p> <p>18 Q But I guess what I'm asking is, is this</p> <p>19 particular section, can it be used in the interim</p> <p>20 should new information come out, should a new</p> <p>21 realization come out of some sort, should there be</p> <p>22 a change of mind or change of heart on an issue by</p> <p>23 a particular panel member, does this section allow</p> <p>24 the CIR to reconvene and -- and reevaluate?</p> <p>25 A It does.</p>

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<p style="text-align: right;">Page 856</p> <p>1 MR. MEADOWS: Tom, I'm glad to keep 2 going or if y'all want -- I know it's been an hour 3 and a half roughly. 4 MR. LOCKE: What would you like to do? 5 THE WITNESS: Keep going. 6 MR. LOCKE: Okay. 7 BY MR. MEADOWS: 8 Q All right. We're still on the CIR. 9 Now, I -- I asked you this a little bit earlier, 10 and you might remember, the -- the CIR executive 11 panel, it is considered the linchpin for industry 12 self-regulation, right? 13 A I'm sorry -- 14 MR. LOCKE: Objection to form, asked and 15 answered. 16 BY MR. MEADOWS: 17 Q Well, we talked about -- 18 A Did you -- you said executive panel. 19 I'm not sure -- do you mean expert panel? 20 Q Yes. 21 A Okay. 22 Q I'm sorry. 23 A No, I just wanted to make sure you 24 didn't mean steering committee. 25 Q Correct.</p>	<p style="text-align: right;">Page 858</p> <p>1 Q And they in fact are the way that the 2 industry has chosen to go about regulating 3 themselves, correct? 4 MR. LOCKE: Objection to form. 5 THE WITNESS: Yeah, I guess I would just 6 go back to back when they were -- when CIR was 7 formed, if FDA had taken that responsibility, you 8 know, that -- that would have been one thing, but 9 when they said they couldn't, industry took it on. 10 BY MR. MEADOWS: 11 Q Well, we talked about that too. It's -- 12 the law doesn't say FDA is responsible for 13 regulating the product. The law says that 14 industry is responsible for regulating their 15 product, correct? 16 MR. LOCKE: Objection to form. 17 THE WITNESS: Yeah, my point was just 18 that if -- if FDA had still -- being in the role 19 of -- with cosmetic -- with the regulation of 20 cosmetics, if they had formed an equivalent to the 21 Cosmetic Ingredient Review expert panel, that -- I 22 mean, that -- if that had been an option, that -- 23 BY MR. MEADOWS: 24 Q Well, had FDA chosen to do that, two 25 things would have had to happen, right? One,</p>
<p style="text-align: right;">Page 857</p> <p>1 A That's -- 2 Q Correct. 3 A That's why I'm saying that. 4 Q The problem is I have the word -- the 5 acronym of "EP" written down here. 6 A Okay. 7 Q That I adopted from -- 8 A Yes. 9 Q -- you said started using it. So -- 10 A Exactly, the one person used it. 11 Q So the CIR expert panel, it is 12 considered the linchpin for industry regulation, 13 right? 14 MR. LOCKE: Objection to form, asked and 15 answered. 16 THE WITNESS: It's -- yeah, it's a very 17 key part, obviously, of the CIR process. 18 BY MR. MEADOWS: 19 Q But, I mean, PCPC is not here to say 20 that the cosmetic industry does not have a 21 responsibility to self-regulate, correct? 22 A The cosmetic industry has a 23 responsibility for their products to be safe 24 before they're put on the market. The CIR is in 25 some ways a confirming -- confirming process.</p>	<p style="text-align: right;">Page 859</p> <p>1 they'd've had to change the law, right? 2 MR. LOCKE: Objection to form, and 3 beyond the scope. 4 THE WITNESS: Not -- I -- 5 BY MR. MEADOWS: 6 Q The law requires cosmetic companies to 7 regulate themselves, correct? 8 A I -- I absolutely agree that -- 9 MR. LOCKE: Objection to form and beyond 10 the scope. 11 THE WITNESS: Yes, industry is required 12 to have products be safe, that's what the law 13 says, before they're put on the market. That's 14 correct. 15 BY MR. MEADOWS: 16 Q The second thing is, if it's shifted to 17 the -- to being the responsibility of the FDA, who 18 pays for that? 19 A No, that's what I was just saying, 20 that -- that -- I mean, CIR formed in part because 21 FDA didn't have the resources. Whatever reason, 22 they didn't have kind of the ingredient review, so 23 industry felt that was something important to do, 24 notwithstanding that, yes, it is industry's 25 obligation to have products be safe before they're</p>

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<p>1 put on market.</p> <p>2 And again, CIR has over the years</p> <p>3 reviewed ingredients. Not all ingredients have</p> <p>4 been reviewed by CIR. I mean, it's a process, so</p> <p>5 industry still has the obligation, and you</p> <p>6 couldn't rely fully on CIR because there would be</p> <p>7 ingredients that have not -- they have not yet</p> <p>8 looked at.</p> <p>9 Q So the answer to my question is, if FDA</p> <p>10 takes on that responsibility, the taxpayer then</p> <p>11 ends up paying to regulate the cosmetic industry,</p> <p>12 correct?</p> <p>13 MR. LOCKE: Objection. Form, beyond the</p> <p>14 scope.</p> <p>15 THE WITNESS: I mean, money -- money to</p> <p>16 FDA is taxpayer money, of course.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Correct.</p> <p>19 A Yes.</p> <p>20 Q All right.</p> <p>21 All right. So let's go to Exhibit 87.</p> <p>22 (Exhibit No. 87 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q All right. So I've marked this as</p>	<p>1 there. Do you see that?</p> <p>2 A Yes.</p> <p>3 Q So this is where I get that language</p> <p>4 from. "The linchpin of our self-regulatory</p> <p>5 programs is the Cosmetic Ingredient Review expert</p> <p>6 panel." Right?</p> <p>7 A Yes.</p> <p>8 Q Okay. And it talks about being</p> <p>9 independent, nonprofit panel of world-renowned</p> <p>10 scientists, right?</p> <p>11 A Yes.</p> <p>12 Q And physicians. It was established in</p> <p>13 '76, right?</p> <p>14 A Yes.</p> <p>15 Q To assess the safety of ingredients used</p> <p>16 in cosmetics in the United States. It says it's</p> <p>17 supported -- with the support of the U.S. Food and</p> <p>18 Drug Administration and the Consumer Federation of</p> <p>19 America. Right?</p> <p>20 A Yes.</p> <p>21 Q Okay. And it talks about in the second</p> <p>22 bullet point self-regulation, Council works to</p> <p>23 uphold and often surpass the most stringent U.S.</p> <p>24 Consumer Products Safety Standards, right?</p> <p>25 A That's what it says, yes.</p>
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<p>1 Plaintiffs' 87. And it is entitled "Personal Care</p> <p>2 Products Council Public Affairs Issues Messaging</p> <p>3 Guide" from 2008, correct?</p> <p>4 A Yes.</p> <p>5 Q And it is a PCPC document from -- with a</p> <p>6 Bates No. 17629, correct?</p> <p>7 A Correct.</p> <p>8 Q Okay. You've seen this before?</p> <p>9 A Possibly.</p> <p>10 Q Well, I just want to focus on a couple</p> <p>11 of pages here. Let's go to page 5.</p> <p>12 Now, first of all, this is a document</p> <p>13 created for what purpose?</p> <p>14 A I guess I could just take it at face</p> <p>15 value that it's -- it must be put together by the</p> <p>16 Public Affairs department.</p> <p>17 Q Okay. In part, maybe to answer</p> <p>18 questions --</p> <p>19 A Sure.</p> <p>20 Q -- regarding the PCPC?</p> <p>21 A Yes.</p> <p>22 Q Okay. All right. So if you look under</p> <p>23 the section "Committed to the Science of Safety."</p> <p>24 A Yes.</p> <p>25 Q And go down, there's three bullets</p>	<p>1 Q Okay. The product safety is the top</p> <p>2 priority of the PCP -- of the personal care</p> <p>3 products industry, right?</p> <p>4 A That's what it says, yes.</p> <p>5 Q It says that: "PCPC works diligently</p> <p>6 with members to maintain the high standards of</p> <p>7 safety rooted in science and cutting edge</p> <p>8 research." Right?</p> <p>9 A Yes.</p> <p>10 Q Do you believe that?</p> <p>11 A Yes.</p> <p>12 Q Okay. If you flip over to the previous</p> <p>13 page, it talks about the personal care products</p> <p>14 industry, the fact that every day millions of</p> <p>15 consumers use cosmetics, right?</p> <p>16 A Yes.</p> <p>17 Q And the personal care products industry</p> <p>18 is a global industry with more than 250 billion in</p> <p>19 annual retail sales, right?</p> <p>20 A That's what it says, yes.</p> <p>21 Q And then it goes on to talk about who</p> <p>22 the Personal Care Products Council is, it's got</p> <p>23 more than 600 members. Right?</p> <p>24 A Right.</p> <p>25 Q At least in 2008.</p>

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<p>1 A Uh-huh.</p> <p>2 Q It used to be called the Cosmetic and</p> <p>3 Toiletry Fragrance Association?</p> <p>4 A That's true.</p> <p>5 Q Correct?</p> <p>6 A Yeah.</p> <p>7 Q It says: "For more than 600 members, we</p> <p>8 are the voice on scientific, legal, regulatory,</p> <p>9 legislative and international issues for the</p> <p>10 personal care product industry." Correct?</p> <p>11 A That's what it says, yes.</p> <p>12 Q "We are a leading and trusted source of</p> <p>13 information for and about the personal care</p> <p>14 products industry, and a vocal advocate for</p> <p>15 consumer safety and continued access to new,</p> <p>16 innovative products." Right?</p> <p>17 A Yes.</p> <p>18 Q "We are a vocal advocate for consumer</p> <p>19 safety." Right?</p> <p>20 A Yes.</p> <p>21 Q And then it goes on to talk about other</p> <p>22 aspects of the PCPC, correct, down at the bottom?</p> <p>23 A Yes.</p> <p>24 Q All right. I guess actually PCPC has</p> <p>25 been around a while, right?</p>	<p>1 Ingredient Review expert panel 30 years ago to</p> <p>2 provide yet another level of protection for</p> <p>3 consumers."</p> <p>4 I read that correctly?</p> <p>5 A Yes.</p> <p>6 Q Do you feel confident that the public</p> <p>7 can count on the CIR expert panel to ensure their</p> <p>8 safety?</p> <p>9 A Again, that's not -- I mean,</p> <p>10 manufacturers are responsible for the safety of</p> <p>11 their products, and CIR is another step that</p> <p>12 provides protection for consumers.</p> <p>13 Q Yeah, manufacturers are responsible. I</p> <p>14 agree with you. They've chosen the CIR expert</p> <p>15 panel to carry out that duty for them, correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 THE WITNESS: I -- I mean, I guess I</p> <p>18 wouldn't say -- no, because I think companies are</p> <p>19 responsible for their own products. And so they</p> <p>20 need internally to know their own products.</p> <p>21 CIR is helpful in that and has now</p> <p>22 reviewed a great deal of ingredients, but</p> <p>23 certainly is -- they have not reviewed all</p> <p>24 ingredients.</p> <p>25 BY MR. MEADOWS:</p>
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<p>1 A A long time.</p> <p>2 Q Founded in 1984.</p> <p>3 A What page are you on?</p> <p>4 Q On page 6. I'm sorry.</p> <p>5 And that's right about the time that</p> <p>6 baby powder came on the market, right?</p> <p>7 A I -- I'm not sure.</p> <p>8 Q Okay. All right.</p> <p>9 Okay. Flip on over to 34 -- page 34,</p> <p>10 that is.</p> <p>11 This appears to be to me -- I mean, if</p> <p>12 you look at the page before, it says -- it's</p> <p>13 entitled "Questions and Answers on Cosmetic Safety</p> <p>14 and Product Testing." Do you see that?</p> <p>15 A Yes.</p> <p>16 Q I'm assuming that these are questions</p> <p>17 that might come from the public or the press or</p> <p>18 something like that, and these are answers that</p> <p>19 the PCPC has approved to -- to get out to the</p> <p>20 public, correct?</p> <p>21 A I would say so, yes.</p> <p>22 Q Number 5. "What additional steps have</p> <p>23 the Personal Care Products Council taken to ensure</p> <p>24 consumer safety?"</p> <p>25 Answer: "We created the Cosmetic</p>	<p>1 Q Yeah. But at the end of the day, the</p> <p>2 CIR expert panel says safe, unsafe. Right?</p> <p>3 A No. There's -- I mean, there's --</p> <p>4 there's more than that. There's safe with</p> <p>5 qualifications. There's safe when -- for example,</p> <p>6 one conclusion is they sometimes put a</p> <p>7 qualification that an ingredient can be irritating</p> <p>8 if it's not skin -- to skin if it's not properly</p> <p>9 formulated. So they would note that. So then the</p> <p>10 company would certainly have the responsibility to</p> <p>11 understand that their particular formulation is</p> <p>12 not irritating.</p> <p>13 But they -- I mean, they have several</p> <p>14 categories, not just safe and unsafe, and probably</p> <p>15 the main one, because it affects a great number of</p> <p>16 ingredients, is they will put qualifications on</p> <p>17 how it can be used: Only used in rinse-off, only</p> <p>18 used in this type of product.</p> <p>19 Q Can you think of any examples of a</p> <p>20 situation where the CIR determined an ingredient</p> <p>21 to be unsafe -- or, excuse me, determined an</p> <p>22 ingredient to be safe, but the company decided</p> <p>23 that it was unsafe in some way, shape or form</p> <p>24 thereafter?</p> <p>25 A I mean, I -- I probably would -- I mean,</p>

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<p>1 you would have to assume a company would contact</p> <p>2 me and tell me that. So -- I mean, so I'm -- I</p> <p>3 don't know that I can answer that. I mean, I</p> <p>4 wouldn't have that information particularly.</p> <p>5 Q Okay. I'm just -- I'm just asking if</p> <p>6 you're aware of any -- any situation where the CIR</p> <p>7 determined an ingredient to be safe, and</p> <p>8 thereafter the company said, Well, we don't think</p> <p>9 it's as safe as they say it is.</p> <p>10 A I can't think of anything like that. I</p> <p>11 mean, there's ingredients that people -- companies</p> <p>12 choose not to use for whatever reason, because</p> <p>13 they say it's in the newspaper a lot with bad</p> <p>14 press, and so -- even though CIR says it's safe,</p> <p>15 they may not use it. But that's not exactly what</p> <p>16 you're asking.</p> <p>17 Q Is it fair to say that the CIR panel</p> <p>18 relies on, in part, the company to provide them</p> <p>19 with truthful and accurate information?</p> <p>20 A They --</p> <p>21 MR. LOCKE: I'm sorry. What company?</p> <p>22 MR. MEADOWS: Any company that has -- is</p> <p>23 having their ingredient reviewed.</p> <p>24 MR. LOCKE: A member company.</p> <p>25 MR. MEADOWS: Correct.</p>	<p>1 regarding an ingredient? Fair to say?</p> <p>2 MR. LOCKE: Objection to form.</p> <p>3 THE WITNESS: I guess one piece of CIR's</p> <p>4 review is -- is knowing how the ingredients are</p> <p>5 used, and they -- that would depend on getting</p> <p>6 information from companies.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q Okay. And, for instance, if when talc</p> <p>9 was reviewed, either Johnson & Johnson or Imerys</p> <p>10 knew of information indicating that their talc</p> <p>11 product or ingredient had been contaminated with</p> <p>12 asbestos at some point in time, it would be</p> <p>13 incumbent upon them to bring that information to</p> <p>14 the attention of the CIR when they're reviewing,</p> <p>15 correct?</p> <p>16 MR. DONATH: Objection to form.</p> <p>17 THE WITNESS: I mean, I guess -- I think</p> <p>18 CIR addressed that issue going back from what was</p> <p>19 in the published literature, and I know that they</p> <p>20 were talking to -- they were looking for</p> <p>21 information from industry on current</p> <p>22 specifications and -- and practices.</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q Yeah. My question is very simple.</p> <p>25 If -- if the information -- if J&J or</p>
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<p>1 THE WITNESS: So I guess when you say</p> <p>2 "their ingredient," I mean, they review those that</p> <p>3 are used throughout the industry, so not for any</p> <p>4 specific company. But when the CIR -- you have to</p> <p>5 understand the CIR process, which is that they go</p> <p>6 out, they do a literature review, you know, so</p> <p>7 they reach out and do a regular review.</p> <p>8 What industry provides, what specific</p> <p>9 companies might provide is data that they have</p> <p>10 that's unpublished, and very often sometimes they</p> <p>11 will provide, for example, a human repeat insult</p> <p>12 patch test, which gets at sensitization, and</p> <p>13 because that's a lot of data that would generally</p> <p>14 not be published, so they would provide that kind</p> <p>15 of information. But they would get reports of</p> <p>16 those kind of studies from industry.</p> <p>17 But for the most part, I mean, where</p> <p>18 they start is they're looking at what -- what</p> <p>19 information is available in the literature, and</p> <p>20 from that they start to build a report.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q But it's fair to say that CIR cannot</p> <p>23 make a solid and correct decision on a particular</p> <p>24 ingredient unless members provide accurate and</p> <p>25 truthful information about what they know</p>	<p>1 Imerys were aware of information showing that</p> <p>2 their product was contaminated with asbestos, and</p> <p>3 nobody else knew that but them, it would be</p> <p>4 incumbent upon them to inform the CIR so that the</p> <p>5 CIR can make an informed decision about the</p> <p>6 product, right?</p> <p>7 MR. DONATH: Objection to form.</p> <p>8 MS. FRAZIER: Objection to form.</p> <p>9 MR. LOCKE: Objection to form.</p> <p>10 THE WITNESS: I mean, if someone has</p> <p>11 information about safety, in general, that's not</p> <p>12 available, obviously CIR can't consider it unless</p> <p>13 they're given that information.</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Okay. Good enough.</p> <p>16 All right. So flipping over to page 67.</p> <p>17 All right. So this is more questions</p> <p>18 and answers on talc, right -- or actually, it's</p> <p>19 Questions and Answers on Talc.</p> <p>20 Did I read that correctly?</p> <p>21 A Yes.</p> <p>22 Q Okay. Number 1. "What about reports</p> <p>23 that claim talc can contain asbestos-like fibers,</p> <p>24 which would be harmful to consumers' health?"</p> <p>25 Answer: "Cosmetic grade talc does not</p>

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<p>1 contain asbestos, which is confirmed by x-ray</p> <p>2 defraction and optical and electron microscopy.</p> <p>3 In addition, the producers of cosmetic grade talc</p> <p>4 have established purity specifications to ensure</p> <p>5 that it does not contain residue levels of</p> <p>6 asbestos."</p> <p>7 Did I read that correctly?</p> <p>8 A You did.</p> <p>9 Q So what PCPC was telling the public is</p> <p>10 that cosmetic grade talc does not contain</p> <p>11 asbestos, and that the industry has testing</p> <p>12 methods to establish purity to ensure that it does</p> <p>13 not contain even residue levels of asbestos.</p> <p>14 Right?</p> <p>15 A I'm not sure if it's telling the public,</p> <p>16 but that is what this document says, yes.</p> <p>17 Q Okay. I thought we established that</p> <p>18 this -- this is a messaging piece that would be</p> <p>19 used to answer public questions, right?</p> <p>20 A I -- I'm not sure what it's used for.</p> <p>21 I'm not saying that that's not used for answering</p> <p>22 the public. I guess just -- it seemed to imply</p> <p>23 this is some public document, and I don't think of</p> <p>24 it as that way.</p> <p>25 Q Well, who would PCPC be messaging?</p>	<p>1 here's -- here's what the data is. And I think</p> <p>2 that's -- to me that's more our public face.</p> <p>3 That's -- I mean, this is just obviously</p> <p>4 an incomplete answer. I mean, you could write</p> <p>5 books about talc and ovarian cancer. So...</p> <p>6 Q Including saying that there's studies</p> <p>7 out there that show that it increases the risk of</p> <p>8 ovarian cancer, right?</p> <p>9 A I think when we -- what we say on the</p> <p>10 cosmeticsinfo.org is -- is accurate and presents</p> <p>11 more than one side.</p> <p>12 Q Including telling the public that Muscat</p> <p>13 and Huncharek are not exactly the most independent</p> <p>14 of experts, right?</p> <p>15 MR. LOCKE: Objection to form.</p> <p>16 THE WITNESS: I mean, I think there's --</p> <p>17 there are mixed opinions on -- on this topic.</p> <p>18 That would be truthful.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Yeah. You would agree with me, though,</p> <p>21 that Muscat and Huncharek are not exactly</p> <p>22 independent, are they?</p> <p>23 MR. LOCKE: Objection to form.</p> <p>24 THE WITNESS: I think you need to look</p> <p>25 at what they say.</p>
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<p>1 A I'm not disagreeing that this was our</p> <p>2 position.</p> <p>3 Q All right. It goes on.</p> <p>4 Number 3. "Some studies have claimed</p> <p>5 that there is a connection between talc and</p> <p>6 ovarian cancer. Is there an established link</p> <p>7 between talc and ovarian cancer?"</p> <p>8 Answer: "Some case controlled</p> <p>9 epidemiology studies in the 1990s reported small</p> <p>10 increases in ovarian cancer among women who use</p> <p>11 talc in the perineal or genital area. However, a</p> <p>12 meta-analysis published in 2007 by Muscat and</p> <p>13 Huncharek shows no association between perineal</p> <p>14 use of talc and ovarian cancer."</p> <p>15 Is that what that says?</p> <p>16 A That's what it says.</p> <p>17 Q Do you think that's an accurate and</p> <p>18 complete answer at that time?</p> <p>19 A I think it's a -- it's very brief and</p> <p>20 arguably incomplete. Again, I don't -- I mean, an</p> <p>21 answer like that, I would not -- I think this is</p> <p>22 pulling together our messaging, and I think if you</p> <p>23 wanted to know what we're telling the public, it</p> <p>24 would be in our cosmeticsinfo.org, which I know</p> <p>25 goes into much more discussion about, you know,</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q What who says?</p> <p>3 A I mean, I know what position they take,</p> <p>4 but I think you have to look at the data and their</p> <p>5 analysis of it.</p> <p>6 Q Well, but my question is simply,</p> <p>7 shouldn't the public know -- if this is an answer</p> <p>8 to the public about whether there's a link between</p> <p>9 ovarian cancer and talc use, shouldn't -- if</p> <p>10 you're going to use Muscat and Huncharek,</p> <p>11 shouldn't the public know that they are not an</p> <p>12 independent source of information?</p> <p>13 MR. LOCKE: Objection to form.</p> <p>14 THE WITNESS: So I know that you asked</p> <p>15 me about is this kind of something that would --</p> <p>16 could be used for public responses, but this is</p> <p>17 not a public response. I mean, to me, this is --</p> <p>18 you would -- this is not something that we would</p> <p>19 tell the public, because it's -- it's obviously</p> <p>20 incomplete, and I would really go with other</p> <p>21 things. I -- this --</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q So you're saying that somebody took the</p> <p>24 time to put together a document, the Personal Care</p> <p>25 Products Council, that has a lot of information in</p>

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<p>1 it, stretches over 75 pages, talks about a lot of</p> <p>2 different ingredients, has questions and answers</p> <p>3 throughout, and is called messaging, but this is</p> <p>4 not something that would have been designed to</p> <p>5 answer public questions?</p> <p>6 A I am saying that the form of this answer</p> <p>7 is not something that would directly go to the</p> <p>8 public.</p> <p>9 Q And how do you know that?</p> <p>10 A Because I've been too involved with</p> <p>11 Public Affairs over the years in putting together</p> <p>12 statements --</p> <p>13 Q You --</p> <p>14 A -- to know that this is a final thing</p> <p>15 that you would tell people. I mean, it doesn't</p> <p>16 even make any sense.</p> <p>17 Q Well, this is not your department,</p> <p>18 though, is it?</p> <p>19 A That's correct.</p> <p>20 Q Who's in charge of this department in</p> <p>21 2008?</p> <p>22 A Probably Kathleen Desio.</p> <p>23 Q So she would know whether or not this</p> <p>24 was used to answer public questions, right?</p> <p>25 MR. LOCKE: Objection to form.</p>	<p>1 MR. LOCKE: If we have it, we produced</p> <p>2 it.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q Have all versions of your website</p> <p>5 cosmeticsinfo.org been produced to us in every</p> <p>6 incarnation as they existed over the years?</p> <p>7 MR. LOCKE: Beyond the scope of this</p> <p>8 witness. Mr. Pollack was designated to testify on</p> <p>9 that topic.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q What's your answer?</p> <p>12 MR. LOCKE: I just told you. She --</p> <p>13 it's beyond the scope.</p> <p>14 THE WITNESS: Yeah, I don't know what</p> <p>15 was --</p> <p>16 MR. MEADOWS: Okay. All right. I'm</p> <p>17 being told that the reporter needs to take a</p> <p>18 break. I'm very sorry.</p> <p>19 THE VIDEOGRAPHER: The time is 10:59</p> <p>20 a m. We're going off the record.</p> <p>21 (Recess.)</p> <p>22 THE VIDEOGRAPHER: The time is 11:13</p> <p>23 a m., and we're back on the record.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q All right. Dr. Loretz, before we move</p>
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<p>1 THE WITNESS: I mean, this was not a</p> <p>2 document that went to the public.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q How do you know that?</p> <p>5 A Because we wouldn't put out a</p> <p>6 messaging guide -- I mean, this is pulling</p> <p>7 together thoughts on messaging on various issues</p> <p>8 that we get. What goes to the public is</p> <p>9 cosmeticsinfo.org, and various statements that we</p> <p>10 put together as -- as issues arise.</p> <p>11 Q But, again, this isn't your department,</p> <p>12 right?</p> <p>13 MR. LOCKE: Objection to form, asked and</p> <p>14 answered.</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q Cosmeticsinfo.org, when did that come</p> <p>17 into being?</p> <p>18 A Roughly -- this is after Pam Bailey took</p> <p>19 over as president, so I want to say probably</p> <p>20 started work on it around 2006.</p> <p>21 Q Okay. So it was up and running in 2008?</p> <p>22 A I think so.</p> <p>23 Q You would have versions of that website</p> <p>24 from 2008 so we can compare it to the messaging</p> <p>25 guide you have here?</p>	<p>1 on, I want to make sure I'm clear on something.</p> <p>2 When we left off, we were talking</p> <p>3 about P -- or Exhibit 87, and it's entitled</p> <p>4 "Personal Care Products Council Public Affairs</p> <p>5 Issues Messaging Guide 2008," correct?</p> <p>6 A Yes.</p> <p>7 Q All right. And you said something</p> <p>8 before we left off. I just want to make sure I'm</p> <p>9 clear on my understanding.</p> <p>10 I believe that you said that this</p> <p>11 document would not go out to the public; is that</p> <p>12 correct?</p> <p>13 A Yes.</p> <p>14 Q Okay. But this document does reflect</p> <p>15 messages that are approved by PCPC to deliver to</p> <p>16 the public, correct?</p> <p>17 A I think -- but not as is. I mean, I</p> <p>18 think when we were talking about it, I think it</p> <p>19 would obviously need further development before it</p> <p>20 would make sense to go out to the public. So</p> <p>21 these are kind of the maybe initial thoughts of</p> <p>22 messaging. Some more developed than others, I</p> <p>23 would assume.</p> <p>24 Q So are you saying this is a draft and</p> <p>25 not a final version of the message that should be</p>

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<p>1 delivered to the public upon inquiry of any 2 particular issue? 3 A What I'm saying is I think this is an 4 internal document. So responding to the public 5 would -- you know, would be -- depend on the 6 specific issue, et cetera. But I don't take these 7 answers as being final answers. I mean, it just 8 depends what the question is, and et cetera. 9 Q Flipping over to -- by the way, when the 10 public does call in with -- or e-mail or in any 11 other mode of communication with questions about 12 particular ingredients and their safety, who 13 handles those calls, any inquiries? 14 MR. LOCKE: Objection to form. 15 THE WITNESS: I would say, in general, 16 Public Affairs department. 17 BY MR. MEADOWS: 18 Q Okay. And so might it be that this 19 particular guide was designed for people in the 20 Public Affairs department so they'd have a quick 21 reference to answer questions upon inquiry? 22 A I'm not sure. I think that was the 23 reason that we developed the website, the 24 cosmeticsinfo.org, because I think a very normal 25 response now would be to refer a consumer to that.</p>	<p>1 in their document their final review that I think 2 was published, correct? 3 A Yes. 4 Q They did address the epidem- -- or at 5 least some of the epidemiology that's out there, 6 correct? 7 A Yes. 8 Q And they reviewed other medical 9 literature and data. 10 A Yes. 11 Q Correct? 12 A Yes. 13 Q But regardless of what they thought 14 about the epi and toxicology and other data, 15 ultimately their decision to determine talc was 16 safe was based on their conclusion that talc does 17 not migrate to the ovaries. 18 MR. LOCKE: Objection. 19 BY MR. MEADOWS: 20 Q Do you agree or not -- disagree with 21 that? 22 A I would have to look at the report 23 wording. 24 Q Well, we'll get to the report in a 25 little bit, but right now we're going to look at</p>
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<p>1 Q All right. And you mentioned that, and 2 I noticed during the break that, indeed, at that 3 time this document reflects on page 4 that the 4 website cosmeticsinfo.org was up and running at 5 that point, correct? 6 A That makes sense, yes. 7 Q Now, we kind of talked about this a 8 little bit, but I think it's worthy of digging 9 down a little bit more into it. 10 The CIR panel, ultimately their decision 11 that talc does not cause ovarian cancer was based 12 on the fact that they said that talc cannot 13 migrate to the ovaries, correct? 14 MR. LOCKE: Objection. 15 THE WITNESS: I don't think it was as 16 simple as that. I think they talked about some of 17 the weaknesses and the epidemiology studies. I 18 think they talked about migration. I'm not sure 19 where their final -- I don't know that they came 20 up with anything that was that final and 21 definitive, but I'd have to look at the report for 22 the exact wording. 23 BY MR. MEADOWS: 24 Q And we'll do that a little bit later. 25 But I think you're right, I think they did address</p>	<p>1 your 2012 annual report. 2 (Exhibit No. 88 was marked for 3 identification.) 4 BY MR. MEADOWS: 5 Q Okay. I've handed you what has been 6 marked as Exhibit 88 from PCPC-MDL-92069. 7 You recognize that document? 8 A I've seen annual reports over the years, 9 but... 10 Q Well, this is the 2012 annual report, 11 right? 12 A Yes. 13 MR. LOCKE: Just to be clear, it's the 14 Cosmetic Ingredient -- 15 THE WITNESS: Yeah. 16 MR. LOCKE: -- Review Annual Report. 17 MR. MEADOWS: Thank you. Good point. 18 BY MR. MEADOWS: 19 Q It's the CIR review annual report for 20 2012, correct? 21 A Correct. Yes. Thank you. 22 Q Okay. So this is -- this is from the 23 same year that talc was reviewed, correct? 24 A I think this was -- that sounds right. 25 Q Okay. Well, maybe we can get more</p>

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<p>1 oriented a little bit by looking at --</p> <p>2 A The reviews run over time. That's why</p> <p>3 I'm being a little bit --</p> <p>4 Q Okay. All right. So we're going to</p> <p>5 look at a particular page, and it's a little</p> <p>6 difficult to navigate this one because we don't</p> <p>7 have page numbers on this document, so you and I</p> <p>8 are going to have to hunt for this together.</p> <p>9 Okay?</p> <p>10 A Yeah.</p> <p>11 Q So there's a section on talc and -- I</p> <p>12 didn't do a good job of marking this myself.</p> <p>13 It's -- to give you a little bit of an idea, maybe</p> <p>14 it's about three-quarters of the way back.</p> <p>15 It's a page -- a page that looks like</p> <p>16 this (indicating), Dr. Loretz.</p> <p>17 A Okay.</p> <p>18 Q If that helps you at all.</p> <p>19 A It looks like I'm -- yeah, there it is.</p> <p>20 Q Okay. And so it's got -- it's got -- to</p> <p>21 make sure we're on the same page, it's got a</p> <p>22 section at the top that says "Nylon Polymers."</p> <p>23 A Right.</p> <p>24 Q You got that. Okay.</p> <p>25 And then we've got one for talc, right?</p>	<p>1 was a causal relationship between ovarian cancer</p> <p>2 and cosmetic use of talc."</p> <p>3 Did I read that correctly?</p> <p>4 A That's what it says, yes.</p> <p>5 Q This is a document that was -- this is</p> <p>6 the CIR annual report that says that, correct?</p> <p>7 A Yes.</p> <p>8 Q Do you disagree with the CIR's own</p> <p>9 interpretation of their conclusion?</p> <p>10 A I mean, I think -- as I say, I think the</p> <p>11 report itself has a much more fulsome discussion</p> <p>12 of the issue of ovarian cancer. And I'm not sure</p> <p>13 that this is the best way that it would be</p> <p>14 captured. It's not my recollection that it is.</p> <p>15 Q Well, this is their own interpretation</p> <p>16 of their own conclusion.</p> <p>17 A I mean, I --</p> <p>18 MR. LOCKE: Of a tentative safety</p> <p>19 assessment.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q You're not brawling about that. This is</p> <p>22 their own interpretation of their own conclusion?</p> <p>23 A This is what they wrote, and as my</p> <p>24 counsel just noted, it is a tentative safety</p> <p>25 assessment. So at this point the report was not</p>
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<p>1 A Yes.</p> <p>2 Q So let me see if I can bring this up a</p> <p>3 little bit.</p> <p>4 All right. We're looking at the CIR</p> <p>5 annual report, right?</p> <p>6 A Yes.</p> <p>7 Q Okay. So under talc, it says: "The CIR</p> <p>8 expert panel issued a tentative safety assessment</p> <p>9 for public comment with the conclusion that talc</p> <p>10 is safe for use as a cosmetic ingredient in</p> <p>11 present practices of use and concentration</p> <p>12 described in the safety assessment."</p> <p>13 It says: "The panel stated that talc</p> <p>14 should not be applied to skin when the epidermal</p> <p>15 barrier is ulcerated or removed."</p> <p>16 Did I -- I read that correctly?</p> <p>17 A Yes, you did.</p> <p>18 Q Okay. Now, if you go on to the next</p> <p>19 paragraph, it says: "The panel noted that</p> <p>20 although numerous studies have been performed to</p> <p>21 examine whether there is a correlation between</p> <p>22 ovarian cancer and talc, the data do not suggest</p> <p>23 that application of talc to the perineal area</p> <p>24 results in migration to the ovaries. Therefore,</p> <p>25 the panel did not think there was causal -- there</p>	<p>1 final.</p> <p>2 Q So you think that interpretation is</p> <p>3 going to change after it's final?</p> <p>4 A I think maybe more importantly is what</p> <p>5 the report says and what it discusses, rather than</p> <p>6 the very brief summary here.</p> <p>7 Q Okay. Well, we're going to get to their</p> <p>8 report eventually.</p> <p>9 But as you sit here today and are</p> <p>10 sitting here right now, are you telling me that</p> <p>11 I'm expecting that we're going to get that report</p> <p>12 and it's going to say something different from</p> <p>13 what we're seeing here in this document?</p> <p>14 A I think it's going to have a better,</p> <p>15 more fulsome discussion of the issue.</p> <p>16 Q All right. Going down to the next</p> <p>17 paragraph. "The panel agree that early analysis</p> <p>18 of the composition of talc in which asbestiform</p> <p>19 fibers were detected may not be relevant to the</p> <p>20 current composition of cosmetic talc because such</p> <p>21 information was developed before asbestos-free</p> <p>22 specifications for talc were developed by the</p> <p>23 cosmetic industry, and unreliable analytical</p> <p>24 methods may have been used."</p> <p>25 Did I read that correctly?</p>

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<p>1 A Yes, you did.</p> <p>2 Q So the way the CIR summarizes their</p> <p>3 conclusion about talc and the possibility of</p> <p>4 asbestos contamination is that current talc is</p> <p>5 asbestos-free, right?</p> <p>6 A Before the specifications were</p> <p>7 developed, yes.</p> <p>8 Q So their decision to say that cosmetic</p> <p>9 talc is safe with respect to asbestos</p> <p>10 contamination was based on their understanding</p> <p>11 that the talc being used is asbestos-free,</p> <p>12 correct?</p> <p>13 A It refers to the development of --</p> <p>14 the -- the specifications for talc.</p> <p>15 Q And it refers to the phrase</p> <p>16 "asbestos-free," right?</p> <p>17 A The specification does say that it's</p> <p>18 free of detectable asbestos.</p> <p>19 Q Where is the word "detectable" in there?</p> <p>20 A I'm saying that's what the specification</p> <p>21 says, and this refers to the specification.</p> <p>22 Q Well, now, there's a difference between</p> <p>23 something being free of something and something</p> <p>24 not having detectable levels, right?</p> <p>25 A Yes. But this refers to the</p>	<p>1 timing, but final, total, complete review.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Well, they issued a -- at least a report</p> <p>4 during 2012, didn't they?</p> <p>5 A Well, it says "Tentative." So, again,</p> <p>6 I'm not sure -- the review was completed in a</p> <p>7 different year.</p> <p>8 Q Well, did it change after the tentative</p> <p>9 report?</p> <p>10 A Usually between the tentative and final,</p> <p>11 there are some differences in the report. It</p> <p>12 doesn't mean the conclusion changed, but...</p> <p>13 Q Okay. So the tentative report reflects</p> <p>14 the conclusions that the ultimate report has,</p> <p>15 right?</p> <p>16 MR. LOCKE: Objection to form.</p> <p>17 THE WITNESS: I don't believe the</p> <p>18 conclusion changed.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Okay. In any event, a big chunk of the</p> <p>21 review of talc was in 2012, right?</p> <p>22 A I believe that would be correct, yes.</p> <p>23 Q And in fact, 2012 was the year, and</p> <p>24 correct me if I'm wrong, in which the CIR reviewed</p> <p>25 more ingredients than they've ever reviewed in the</p>
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<p>1 specification, and it goes back to the</p> <p>2 specification, which says "no detectable."</p> <p>3 Q Do you think "asbestos-free" means the</p> <p>4 same thing as "no detectable asbestos"?</p> <p>5 MR. LOCKE: Objection to form.</p> <p>6 THE WITNESS: "Free from detectable</p> <p>7 asbestos," I believe is what the specification</p> <p>8 says.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q But that's not what the summary of the</p> <p>11 CIR -- of this -- that's not how the CIR</p> <p>12 summarizes their conclusion, is it?</p> <p>13 MR. LOCKE: Objection to form.</p> <p>14 THE WITNESS: I think because they refer</p> <p>15 to the specification, that that's what they mean.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q Okay. We will look at that report a</p> <p>18 little bit later too.</p> <p>19 All right. Now, 2012, the year talc was</p> <p>20 reviewed, right?</p> <p>21 A Yes. Or again, it was reviewed -- at</p> <p>22 least part of the review took place.</p> <p>23 THE REPORTER: I'm sorry?</p> <p>24 THE WITNESS: At least part of the</p> <p>25 review took place. I'm not sure of the exact</p>	<p>1 history of the CIR.</p> <p>2 A I don't know that to be true, but that</p> <p>3 could be. They were definitely doing a lot more</p> <p>4 grouping, and that was something that they hadn't</p> <p>5 emphasized earlier.</p> <p>6 Q Grouping?</p> <p>7 A Grouping ingredients that were -- had</p> <p>8 similarity so that they could be reviewed in a</p> <p>9 single report.</p> <p>10 (Exhibit No. 89 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Okay. Let me show you what I marked as</p> <p>14 Plaintiffs' 89.</p> <p>15 I handed you Plaintiffs' 89. It's</p> <p>16 Bates-stamped PCPC-MDL-20026. Is that correct?</p> <p>17 A Yes.</p> <p>18 Q Okay. And this document is entitled</p> <p>19 "Cosmetic Ingredient Review. Assessing the safety</p> <p>20 of cosmetic ingredients recent case studies,</p> <p>21 presented at the workshop for Risk Assessment of</p> <p>22 Cosmetics in Seoul, Korea."</p> <p>23 Did I read that correctly?</p> <p>24 A You did.</p> <p>25 Q And Bart Heldreth I assume is -- was the</p>

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<p>1 presenter. Is that --</p> <p>2 A Yes.</p> <p>3 Q -- the way you read it?</p> <p>4 A Yes.</p> <p>5 Q Do you know Bart?</p> <p>6 A Yes.</p> <p>7 Q What's Bart's role with the CIR?</p> <p>8 A At the time of this, he was a Ph.D.</p> <p>9 chemist. He is now the director of CIR.</p> <p>10 Q Okay. And so this appears to be a</p> <p>11 PowerPoint presentation; is that right?</p> <p>12 A It looks like it.</p> <p>13 Q Looks like it. Okay.</p> <p>14 And then there's -- if you'll flip</p> <p>15 over -- yeah, I've got it flagged for you since</p> <p>16 it's not -- it's not numbered there.</p> <p>17 He has a graph in there. It's entitled</p> <p>18 "Five-Year Accomplishments: Greater than 600</p> <p>19 ingredients estimated to be reviewed in 2013."</p> <p>20 Did I read that correctly?</p> <p>21 A Yes.</p> <p>22 Q Okay. And then -- actually, I think I</p> <p>23 got my question wrong a few minutes ago.</p> <p>24 The most that were ever reviewed, at</p> <p>25 least according to this, was 2010, right?</p>	<p>1 I'm --</p> <p>2 A Similar chemistry, so that -- that data</p> <p>3 could be used to read across from one ingredient</p> <p>4 to another where you could spell out a grid where</p> <p>5 there was data that could be used to apply to</p> <p>6 other ingredients within that.</p> <p>7 Q Okay.</p> <p>8 A And -- and -- I mean, and looking -- and</p> <p>9 also just making the effort to put them together</p> <p>10 so that -- kind of efficiency to do a greater</p> <p>11 number of ingredients.</p> <p>12 Q All right. And were there more people</p> <p>13 that got involved between 2009 and 2010?</p> <p>14 A Yes. I think that was the year when</p> <p>15 they hired the -- there was a kind of an expansion</p> <p>16 of CIR. That's when they first hired a Ph.D.</p> <p>17 toxicologist and also a Ph.D. chemist. That would</p> <p>18 be Bart Heldreth.</p> <p>19 And I think they did add a couple of</p> <p>20 other -- maybe a support person. I think they</p> <p>21 added a librarian. I think he was involved with</p> <p>22 publication, to help that along. And I believe</p> <p>23 they may have added another writer.</p> <p>24 Q Okay. Obviously, that requires money,</p> <p>25 right?</p>
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<p>1 A That's what I would read it as, yes.</p> <p>2 Q Where they had -- the CIR reviewed</p> <p>3 almost 700 in 2010, correct?</p> <p>4 A Yes.</p> <p>5 Q The year before that, they reviewed 103</p> <p>6 in 2009, right?</p> <p>7 A Correct.</p> <p>8 Q Why the marked -- or the enormous</p> <p>9 increase?</p> <p>10 A I think they were making an effort to</p> <p>11 review more ingredients, but they were grouping</p> <p>12 them together to use, you know, data from certain</p> <p>13 ingredients, and obviously this can only be done</p> <p>14 when there's enough similarity to -- to do that.</p> <p>15 So they were making an effort to review</p> <p>16 more ingredients, but of course -- and so that</p> <p>17 means -- I don't think they did more reports</p> <p>18 necessarily. It was more ingredients within</p> <p>19 single reports, although that doesn't, of course,</p> <p>20 apply to talc, which doesn't have anything that it</p> <p>21 can really be reviewed with.</p> <p>22 Q All right. So I'm not sure I completely</p> <p>23 understand.</p> <p>24 They were grouping types of ingredients,</p> <p>25 is that -- that had similar characteristics or --</p>	<p>1 A Yes.</p> <p>2 Q And how was -- how was it that the money</p> <p>3 was there for -- for that expansion?</p> <p>4 A It was a conscious effort to kind of</p> <p>5 upgrade CIR to -- and again, remember the expert</p> <p>6 panel is the one actually doing the reviews, but</p> <p>7 this is the front end. It was a conscious effort</p> <p>8 to upgrade, to add some more Ph.D. expertise,</p> <p>9 where they hadn't had a Ph.D. person before other</p> <p>10 than, I believe, just the director. Or maybe</p> <p>11 the -- and also the associate director.</p> <p>12 So it was an effort to, you know, how</p> <p>13 can we make CIR better. It's been in existence a</p> <p>14 long time, how can we make it better.</p> <p>15 Q So was the expansion only as to -- I'll</p> <p>16 call it front-end type efforts -- and let me -- I</p> <p>17 tell you what, let me ask it this way so that</p> <p>18 question will make sense.</p> <p>19 Was there an expansion of the expert</p> <p>20 panels so that they could address more</p> <p>21 ingredients, or was the expansion only as to what</p> <p>22 I would guess I would call front-end people who</p> <p>23 are preparing information for an expert panel to</p> <p>24 review?</p> <p>25 A I'm not sure what time the chemists were</p>

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<p>1 added, what year the chemists were added. That</p> <p>2 may -- that was around the same time to expand to</p> <p>3 that, and that kind of related to the idea if</p> <p>4 you're going to start grouping ingredients and</p> <p>5 talk about similarity, then having some more</p> <p>6 chemists -- chemistry expertise would be</p> <p>7 important. So I believe that did happen around</p> <p>8 the same time.</p> <p>9 Q Okay. And I got a little lost, and it's</p> <p>10 completely my fault.</p> <p>11 But I guess the simple question would</p> <p>12 be, was there an expansion with respect to expert</p> <p>13 panels?</p> <p>14 A And my answer is, yes, I believe it was</p> <p>15 right around that time that they added the two</p> <p>16 chemistry experts to the expert panel.</p> <p>17 Q Okay. All right. Now, going back to my</p> <p>18 question about money, obviously this required --</p> <p>19 this required additional money in order to pay the</p> <p>20 salaries of those on the front end and to pay, I</p> <p>21 guess, consultants to serve on the expert panels,</p> <p>22 correct?</p> <p>23 A That's correct.</p> <p>24 Q Okay. So did that mean -- did CIR --</p> <p>25 or, excuse me, did PCPC have money saved up to</p>	<p>1 Q Had there been -- and it appears in 2012</p> <p>2 when talc was reviewed, the number had gone from</p> <p>3 687 down to 470. Is that right?</p> <p>4 A Yes, mm-hmm.</p> <p>5 Q Was there a reduction in resources or</p> <p>6 did that -- was that a function of the way or --</p> <p>7 and the types of ingredients that were grouped?</p> <p>8 A That would be because of the ingredients</p> <p>9 that come up. And -- and, you know, there can be</p> <p>10 a single ingredient where the group is very large,</p> <p>11 and that helps drive these numbers. So there</p> <p>12 could have been, you know, a couple of those huge</p> <p>13 ingredients in this year, and that could drive the</p> <p>14 difference. So it's -- it's just kind of what</p> <p>15 ingredients were reviewed.</p> <p>16 Q Okay. And was talc -- was there a</p> <p>17 conscious effort to group it with something in</p> <p>18 particular, or was it a -- an entity on its own?</p> <p>19 A Talc was seen as a standalone ingredient</p> <p>20 that couldn't appropriately be grouped with</p> <p>21 anything else.</p> <p>22 Q Okay. Had there been -- do you know, if</p> <p>23 we had this graph extend on out to today, would we</p> <p>24 be seeing substantial increases or substantial</p> <p>25 decreases or about the same?</p>
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<p>1 make this expansion, or did PCPC do something in</p> <p>2 the way of an increase in dues or some sort of</p> <p>3 fundraising in order to make this expansion?</p> <p>4 MR. LOCKE: I'm going to object to the</p> <p>5 extent it's beyond the scope of this witness.</p> <p>6 That was really a topic that Mr. Pollack either</p> <p>7 addressed or was prepared to address.</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q Do you know?</p> <p>10 A I -- I would just say the expense had to</p> <p>11 be approved by the board, and it -- and it was. I</p> <p>12 mean, it was significant enough that it was -- it</p> <p>13 was something that had to be approved. But as to</p> <p>14 whether there was -- that resulted from a raise in</p> <p>15 dues, I'm not sure.</p> <p>16 Q You're not sure.</p> <p>17 A Yeah.</p> <p>18 Q Okay. Good enough.</p> <p>19 But in any event, it resulted in being</p> <p>20 able under the -- under the system to be able to</p> <p>21 review more ingredients on behalf of your members.</p> <p>22 A Correct.</p> <p>23 Q So in 2010, according to this graph, we</p> <p>24 see a spike, I guess, or at least on this graph.</p> <p>25 A Yes.</p>	<p>1 A I think there might be minor --</p> <p>2 relatively minor decreases.</p> <p>3 Q Now, if we flip over to the next page,</p> <p>4 I -- actually, before we flip over to that next</p> <p>5 page, we're going to flip back to where we were.</p> <p>6 The -- is it fair to say PCPC is a</p> <p>7 five-day-- week, 9:00 to 5:00 office, or is --</p> <p>8 does PCPC work and are they open on the weekends?</p> <p>9 A We are not open on the weekends.</p> <p>10 Q Okay. Same with the CIR?</p> <p>11 A Yes.</p> <p>12 Q They are a five-day-a-week work --</p> <p>13 traditional workweek.</p> <p>14 A Correct.</p> <p>15 Q All right. And just doing some math on</p> <p>16 the 2010 year, it would appear that if you take a</p> <p>17 vacation, you've still got CIR doing three reviews</p> <p>18 per day. Does that sound about right?</p> <p>19 MR. LOCKE: Objection to form.</p> <p>20 THE WITNESS: See, I wouldn't qualify</p> <p>21 that. I mean, we're talking about a single report</p> <p>22 that might have -- in the maximum cases, might</p> <p>23 have 200 ingredients. So, yes, of course, there's</p> <p>24 a lot of work to integrate for the various</p> <p>25 ingredients, but it's not the same amount of work</p>

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<p>1 to do -- create 200 reports.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q I guess I'm not following you. Why</p> <p>4 would it not be the same amount of work for each</p> <p>5 report?</p> <p>6 A Because you're using -- you're doing a</p> <p>7 single ingredient, and you're pulling all together</p> <p>8 the data that's available, but it's -- it's not</p> <p>9 the same -- in some of these you might have</p> <p>10 related ingredients, and there's -- it's not that</p> <p>11 they're going to have massive amounts of data on</p> <p>12 each ingredient. They're going to be able to</p> <p>13 group them in ways and use the data. So it's</p> <p>14 not -- it just -- that report is not going to be</p> <p>15 200 times as big as another report.</p> <p>16 Q Okay. In any event, I think we -- you</p> <p>17 just said it a few minutes ago, talc was not</p> <p>18 grouped. It was treated specially compared to the</p> <p>19 other ingredients.</p> <p>20 A They're all treated kind of</p> <p>21 individually. I mean, there are other ingredients</p> <p>22 that are done singly. There's -- it's not</p> <p>23 uncommon to have, say, three ingredients in a</p> <p>24 group, and then there's a -- there's a few that</p> <p>25 lend themselves to very large groups.</p>	<p>1 various categories that fall inside the continuum</p> <p>2 of safe to unsafe, correct?</p> <p>3 A That's correct.</p> <p>4 Q All right. In that period of time, 25,</p> <p>5 35 -- what, 37 years? Am I counting it right?</p> <p>6 A I got 36, yeah, but whatever.</p> <p>7 Q Okay. 3,156 reviewed and only 11 were</p> <p>8 found to be unsafe. Did I read that correctly?</p> <p>9 A You did. But can I comment on that</p> <p>10 or --</p> <p>11 Q No. I'll ask you if I need a comment.</p> <p>12 Thank you.</p> <p>13 A Okay.</p> <p>14 Q Now, there was some talk yesterday about</p> <p>15 IARC. And I believe your comment was that it's a</p> <p>16 -- it's not a transparent process.</p> <p>17 Am I saying that correctly?</p> <p>18 A I think I would say not -- not open.</p> <p>19 Q Not open.</p> <p>20 A Yeah.</p> <p>21 Q Okay. Now, do you find IARC to be a</p> <p>22 reputable review board, if you will?</p> <p>23 MR. LOCKE: Objection. Asked and</p> <p>24 answered.</p> <p>25 THE WITNESS: Overall, I'm going to say</p>
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<p>1 Q All right. Now, let's flip over to the</p> <p>2 next page.</p> <p>3 Okay. So this slide captures some</p> <p>4 statistics, right?</p> <p>5 A Yes.</p> <p>6 Q Okay. And what I'm seeing on here is</p> <p>7 that CIR -- we know -- I think we've already</p> <p>8 talked about that CIR came into existence in '76,</p> <p>9 right?</p> <p>10 A Correct.</p> <p>11 Q Okay. And so as of the time this</p> <p>12 PowerPoint was done, it looked like, according to</p> <p>13 this PowerPoint, there's over 3,100 ingredients</p> <p>14 that had been reviewed, right?</p> <p>15 A Yes.</p> <p>16 Q All right. And then it has -- it breaks</p> <p>17 down how each of those were categorized, correct?</p> <p>18 A Yes.</p> <p>19 Q So we got the total down here.</p> <p>20 And of the 3 -- of the 3,156 ingredients</p> <p>21 that had been reviewed since 1976, as of 2012,</p> <p>22 over 2,000 of them had been determined to be safe,</p> <p>23 right?</p> <p>24 A Correct.</p> <p>25 Q And you mentioned earlier that there are</p>	<p>1 yes.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Okay. Have you ever compared the</p> <p>4 numbers between IARC's review rate and -- and how</p> <p>5 they go about determining carcinogenicity?</p> <p>6 A It's a very different review from CIR.</p> <p>7 Q I agree.</p> <p>8 A Very, very different.</p> <p>9 Q Okay.</p> <p>10 A It's not -- it's -- the types of</p> <p>11 ingredients, when they're grouped, the big</p> <p>12 groups -- I mean, these are -- again, these are</p> <p>13 cosmetic use. CIR is reviewing ingredients that</p> <p>14 are actually used, and a lot of these are very</p> <p>15 innocuous types of ingredients of similar</p> <p>16 structure. They don't have the complexity of an</p> <p>17 IARC, so the numbers comparison is apples to</p> <p>18 oranges.</p> <p>19 Q Okay. And IARC has a pretty</p> <p>20 sophisticated process, right?</p> <p>21 A Yes.</p> <p>22 Q And the ultimate product that they put</p> <p>23 out is quite a tome, isn't it. It's a large --</p> <p>24 A Large monograph.</p> <p>25 Q Right.</p>

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<p>1 A Yes.</p> <p>2 Q You've seen those before. As a</p> <p>3 toxicologist, you've looked at IARC monographs</p> <p>4 before, correct?</p> <p>5 A Yes.</p> <p>6 Q And they're quite extensive, aren't</p> <p>7 they?</p> <p>8 A They are.</p> <p>9 Q And they're -- the people who do the</p> <p>10 reviews on those panels are people who specialize</p> <p>11 in the issues that are -- on the issues that are</p> <p>12 at stake in a particular review, right?</p> <p>13 A Yes.</p> <p>14 Q So if -- if cancer is a potential issue,</p> <p>15 they've got the best cancer people in the world on</p> <p>16 those panels, right?</p> <p>17 A They -- they have cancer specialists.</p> <p>18 Q And if there's some sort of subspecialty</p> <p>19 issue for a particular ingredient or -- then they</p> <p>20 have a subspecialist who specializes in that</p> <p>21 particular area, right?</p> <p>22 A I -- I'm not sure I can really answer</p> <p>23 that. I'm not going to disagree, though.</p> <p>24 Q Well, certainly if they're dealing with</p> <p>25 epidemiology, they have epidemiologists that serve</p>	<p>1 the scope.</p> <p>2 THE WITNESS: I -- I mean, in general,</p> <p>3 I'm going to say yes.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q Okay. And if CIR was going to decide an</p> <p>6 issue -- if they decided this issue based on</p> <p>7 migration, would you expect them to review the</p> <p>8 entire body of literature pertaining to migration</p> <p>9 before making that decision?</p> <p>10 A I mean, I'm familiar with the CIR</p> <p>11 report. I -- I -- and we looked at more than</p> <p>12 migration.</p> <p>13 Q I understand. That's why I asked the</p> <p>14 question the way I did.</p> <p>15 You and I differ, right, on -- on the</p> <p>16 deciding factor that CIR had with respect to the</p> <p>17 reason they said that talc does not cause ovarian</p> <p>18 cancer, right?</p> <p>19 A I just --</p> <p>20 MR. LOCKE: Objection to form.</p> <p>21 THE WITNESS: I know that they also</p> <p>22 looked at the studies as well. They didn't just</p> <p>23 say, We conclude it doesn't migrate, end of</p> <p>24 discussion.</p> <p>25 BY MR. MEADOWS:</p>
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<p>1 on the panel, right?</p> <p>2 A I believe that is true.</p> <p>3 Q Okay. And we've talked about how CIR</p> <p>4 does not have an epidemiologist on the panel,</p> <p>5 right?</p> <p>6 A That's true.</p> <p>7 Q Okay. They don't have experts with</p> <p>8 subspecialties on the panel, right?</p> <p>9 A It's a standing -- standing group.</p> <p>10 Q Standing group. All right.</p> <p>11 Another difference between IARC and CIR</p> <p>12 is that CIR is directly funded by the very</p> <p>13 industry that wants their -- their ingredient</p> <p>14 reviewed, right?</p> <p>15 A CIR is funded by industry. That's</p> <p>16 correct.</p> <p>17 Q IARC is not funded by industry, is it?</p> <p>18 A No.</p> <p>19 Q And as you say, it's not -- IARC is not</p> <p>20 an open process, is it?</p> <p>21 A It's not.</p> <p>22 Q Do you believe a reviewing body should</p> <p>23 thoroughly review the entire body of literature</p> <p>24 before deciding an issue?</p> <p>25 MR. LOCKE: Objection to form and beyond</p>	<p>1 Q And I'm not disagreeing with you on</p> <p>2 that. What I disagree with you on is -- well, I</p> <p>3 will agree with you that they did look at medical</p> <p>4 literature. They did look at a body of literature</p> <p>5 that pertains to talc and cancer. You and I can</p> <p>6 agree with -- on that.</p> <p>7 A Okay.</p> <p>8 Q Okay. My question is if, if I'm right,</p> <p>9 and their decision to determine talc is safe was</p> <p>10 based on the fact that they don't think talc can</p> <p>11 migrate, would you expect that they -- they should</p> <p>12 and would have looked at the entire body of</p> <p>13 literature pertaining to migration?</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: I mean, I think they would</p> <p>16 look at all the literature that they can find</p> <p>17 related to the topic, yes.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q And they should take that into account</p> <p>20 and weigh it accordingly. Is that fair to say?</p> <p>21 A Sure.</p> <p>22 Q And fair to say that in that process</p> <p>23 that they would not rely heavily on studies that</p> <p>24 were funded by the same organizations that are</p> <p>25 paying their salaries and being funded by the</p>

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<p>1 companies' products?</p> <p>2 MR. LOCKE: Objection to form and beyond</p> <p>3 the scope.</p> <p>4 THE WITNESS: I think that they should</p> <p>5 look at the scientific validity -- validity of the</p> <p>6 literature.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q And should they give more or less weight</p> <p>9 to studies that are funded by the industry that's</p> <p>10 asking that their ingredient be approved?</p> <p>11 MR. LOCKE: Objection. Form and beyond</p> <p>12 the scope.</p> <p>13 THE WITNESS: I think they should weigh</p> <p>14 the studies according to their scientific</p> <p>15 validity.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q I just got a couple of exhibits that I</p> <p>18 have some just general questions about.</p> <p>19 (Exhibit No. 90 was marked for</p> <p>20 identification.)</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q I'm going to show you what I've marked</p> <p>23 as Exhibit 90.</p> <p>24 And it -- it's Bates-numbered PCPC --</p> <p>25 I'm going to say 1387 is the top number there. Do</p>	<p>1 at the document that those who are on the</p> <p>2 committee are -- are from industry, right?</p> <p>3 A Correct. They're from our member</p> <p>4 companies.</p> <p>5 Q This particular document shows that a</p> <p>6 meeting was held in Washington, D.C., on</p> <p>7 December 12, 2000, right?</p> <p>8 A Yes.</p> <p>9 Q And you have various companies,</p> <p>10 including Colgate, Palmolive, Unilever, and</p> <p>11 there's Johnson & Johnson on there.</p> <p>12 And then we got you on there, right?</p> <p>13 A Yes.</p> <p>14 Q Okay. And in fact, this document may</p> <p>15 have actually been drafted by you.</p> <p>16 A I'm pretty darn sure it was.</p> <p>17 Q Okay. You handle the minutes?</p> <p>18 A I do.</p> <p>19 Q Okay. All right. And so I wanted to</p> <p>20 flip over to third page. Under Section C, "CIR</p> <p>21 Issues." Now, we're in 2000, right?</p> <p>22 A Yes.</p> <p>23 Q Okay. So we have a Section 1: "The</p> <p>24 outcome of a CIR coordinating and strategy</p> <p>25 subgroup conference call was discussed," and it's</p>
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<p>1 you agree with me?</p> <p>2 A Yes.</p> <p>3 Q Okay.</p> <p>4 MR. MEADOWS: Is that the number I</p> <p>5 should use?</p> <p>6 MS. TUCKER: The one down at the bottom.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q Oh, I'm told I should use the bottom</p> <p>9 number. So PCPC 82732. We're on the same page,</p> <p>10 right?</p> <p>11 A Yes.</p> <p>12 Q Okay. So can you tell me what this is?</p> <p>13 A These are minutes from a meeting of one</p> <p>14 of the CTFA, at the time, standing committee, the</p> <p>15 Safety and Regulatory Toxicology Committee.</p> <p>16 Q Okay. And then -- the CTFA Safety and</p> <p>17 Regulatory Toxicology Committee. Tell me what is</p> <p>18 that committee.</p> <p>19 A It's a committee of mostly toxicologists</p> <p>20 that -- it's a standing committee. It's been</p> <p>21 around as long as I've been around. It used to be</p> <p>22 known as the PharmTox Committee, and as I say,</p> <p>23 they're mostly toxicologists, and they meet</p> <p>24 quarterly generally.</p> <p>25 Q Okay. And it appears just from looking</p>	<p>1 got the participants on the call, including you.</p> <p>2 The question I have has to do with</p> <p>3 Section B. "A show of hands revealed that few</p> <p>4 SRTC members have actually attended a CIR expert</p> <p>5 panel meeting. It was noted that input from</p> <p>6 outside attendees is welcome at the meetings and</p> <p>7 can have a major impact on the outcome of the</p> <p>8 deliberations. This is especially true on the</p> <p>9 first day of the two-day meeting, when the team</p> <p>10 members have their initial discussion of the</p> <p>11 ingredient issues. SRTC members were encouraged</p> <p>12 to attend CIR meetings to improve their</p> <p>13 understanding of the process."</p> <p>14 Tell me about that.</p> <p>15 A So I don't recall this particular</p> <p>16 strategy subgroup because it's been too long. But</p> <p>17 as I say, the CIR meetings are very open. On the</p> <p>18 first day, which is open to the public, is they</p> <p>19 split into two sub-teams, and there's now --</p> <p>20 although this wasn't true then, at the time there</p> <p>21 were six expert panel members, now there's eight.</p> <p>22 They split into two teams of four, and the expert</p> <p>23 panel discusses the ingredients and where they</p> <p>24 came out, and what their comments were from their</p> <p>25 individual reviews that they bring into the</p>

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<p>1 meeting.</p> <p>2 It's an expert panel discussion, but</p> <p>3 there is allowance for people outside to offer up</p> <p>4 information. For example, if somebody -- if an</p> <p>5 expert panel member were to identify a data gap,</p> <p>6 someone might say, you know, We're aware that</p> <p>7 there is data, we can provide that, or something</p> <p>8 along those lines. But they come to their -- a</p> <p>9 team will come to their position.</p> <p>10 And then on day two, which is also</p> <p>11 public, although much less -- much less</p> <p>12 opportunity for any kind of public input, then the</p> <p>13 teams get together, they say where they came out</p> <p>14 the day before, and they reconcile to a position.</p> <p>15 Q Okay. Now, you say this is an open</p> <p>16 process, right?</p> <p>17 A Yes.</p> <p>18 Q Okay. So my question is, is there ever</p> <p>19 a point in time when the voting panel members meet</p> <p>20 in private?</p> <p>21 A No.</p> <p>22 Q Okay.</p> <p>23 A Yeah, as I say, day two is different,</p> <p>24 has a different dynamic in that it's the people at</p> <p>25 the table. There's a single table that's got the</p>	<p>1 data. Again, this is outside published data. I</p> <p>2 mean, there's published data which obviously the</p> <p>3 CIR staff can find on their own, but looking for</p> <p>4 data that the industry might have.</p> <p>5 So, you know, we try to encourage</p> <p>6 involvement and understanding of the process so</p> <p>7 that people know that if they have something</p> <p>8 that's -- to contribute, that they have the</p> <p>9 opportunity to do so.</p> <p>10 Q All right. Just aside from this, I'm</p> <p>11 just putting this aside, just generally the CIR</p> <p>12 review process of an ingredient, I have a question</p> <p>13 about that, and with respect to the transparency</p> <p>14 and openness, as you call it.</p> <p>15 Is there ever an opportunity for the</p> <p>16 voting members to meet privately and call into</p> <p>17 question some of the information that they're</p> <p>18 getting from the companies on a particular</p> <p>19 ingredient?</p> <p>20 A They don't meet privately. They can</p> <p>21 certainly question something that's in front of</p> <p>22 them openly.</p> <p>23 Q But, I mean, if they do that, then</p> <p>24 they're questioning it right in front of the</p> <p>25 people who are paying their salary, right?</p>
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<p>1 members, and then the liaison members sit there.</p> <p>2 And as I say, mostly -- mostly they -- they can</p> <p>3 either say something, if appropriate, or they</p> <p>4 can -- they might be called on, for example, the</p> <p>5 FDA. And at that point, audience really can't</p> <p>6 input unless they have something very specific to</p> <p>7 say or questions on the table.</p> <p>8 So that's -- that's really a discussion</p> <p>9 that I would say, you know, the public is not</p> <p>10 really involved in the same way they are the first</p> <p>11 day. But they don't meet in private, to answer</p> <p>12 your question.</p> <p>13 Q Okay. So on this particular issue</p> <p>14 that's reflected in this document, what we're</p> <p>15 talking about here is this would be, what, the day</p> <p>16 before the expert panel gets together to start</p> <p>17 discussing a particular issue?</p> <p>18 A I think this subgroup would have been --</p> <p>19 would have been, in general, on CIR. It's not</p> <p>20 specific to a CIR meeting or an ingredient issue.</p> <p>21 Q Oh, okay. So this is -- this is not</p> <p>22 talking about a particular ingredient issue.</p> <p>23 A No. No. This is -- in general, we want</p> <p>24 our members to be aware, and part of it is that --</p> <p>25 part of the CIR process is industry providing</p>	<p>1 MR. LOCKE: Objection to form.</p> <p>2 THE WITNESS: I mean, I guess one</p> <p>3 could -- certainly I -- you know, I can imagine</p> <p>4 where they would look at something and say, This</p> <p>5 seems inconsistent with what we have over here,</p> <p>6 you know.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q Yeah. It's a little different, though,</p> <p>9 than having the freedom to say, I don't think</p> <p>10 we're getting the whole truth here. Right?</p> <p>11 I mean, if you call into question</p> <p>12 whether or not a company is giving you all the</p> <p>13 information, then you're not going to look -- be</p> <p>14 looked upon too good by that company, right?</p> <p>15 A Well, I mean --</p> <p>16 MR. LOCKE: Objection to form.</p> <p>17 THE WITNESS: -- if they think there's</p> <p>18 data out there that they're not getting, they can</p> <p>19 certainly ask for that too.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q Mm-hmm. But then the company knows that</p> <p>22 they're snooping around, right?</p> <p>23 MR. LOCKE: Objection to form.</p> <p>24 THE WITNESS: Well, I guess maybe not</p> <p>25 snooping around. Maybe asking for data.</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q And, I mean, carrying this all the way</p> <p>3 through, at the end of the day, the -- the voting</p> <p>4 members, ultimately their votes are public as</p> <p>5 well, right?</p> <p>6 A The outcomes of the CIR meetings are</p> <p>7 public, yes.</p> <p>8 Q Okay. So if somebody on the panel votes</p> <p>9 unsafe, then the companies who have an ingredient</p> <p>10 at stake are going to know that, right?</p> <p>11 A Yes.</p> <p>12 Q The very companies that are paying their</p> <p>13 salaries and their compensation, correct?</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: I mean, CIR is -- is</p> <p>16 funded by the industry, that's correct.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Mm-hmm. Can you see where somebody</p> <p>19 might question whether or not the process does not</p> <p>20 encourage a healthy and thorough investigation of</p> <p>21 an ingredient?</p> <p>22 A I mean, I would agree that it's funded</p> <p>23 by industry, and as I -- as I said, that was kind</p> <p>24 of set in place because we thought that was better</p> <p>25 to have a CIR than not to have a CIR.</p>	<p>1 A Yes.</p> <p>2 Q Okay. And it appears to be a draft</p> <p>3 telephone conference summary, PCPC/FDA,</p> <p>4 November 4, 2009. Right?</p> <p>5 A Yes.</p> <p>6 Q It does not appear that you were</p> <p>7 involved -- forgive me, but my memory has failed</p> <p>8 me as to when you got there, but --</p> <p>9 A Oh, I was -- I was at the Council, but I</p> <p>10 was not on this call, no.</p> <p>11 Q Okay. And it appears that there's</p> <p>12 some -- that this draft summarizes issues --</p> <p>13 status of issues and points discussed and</p> <p>14 follow-up items, right?</p> <p>15 A That's what it says, yes.</p> <p>16 Q If you flip over to the second page, and</p> <p>17 go down to under Section 5.</p> <p>18 A Okay.</p> <p>19 Q "FDA recognition of CIR findings." And</p> <p>20 you go down -- one, two, three, four -- the fourth</p> <p>21 bullet point -- one, two, three, four -- it says:</p> <p>22 "Dr. Katz" -- who is Dr. Katz?</p> <p>23 A She is the head of the office of -- she</p> <p>24 works for FDA, she is the head of the Office of</p> <p>25 Cosmetics and Colors.</p>
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<p>1 Q Mm-hmm. Now, the decision that is made</p> <p>2 by an CI -- a CIR expert panel, what weight does</p> <p>3 that have with the FDA?</p> <p>4 MR. LOCKE: Objection to form and beyond</p> <p>5 the scope.</p> <p>6 THE WITNESS: I think FDA has</p> <p>7 consistently said that they take into account CIR</p> <p>8 conclusions. It's one piece of evidence.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Okay. But they don't -- the FDA does</p> <p>11 not adopt a CIR finding, does it?</p> <p>12 A That's true.</p> <p>13 Q In fact, the FDA has specifically said</p> <p>14 that, correct?</p> <p>15 A They have.</p> <p>16 Q Okay. I want to look at Exhibit 91.</p> <p>17 (Exhibit No. 91 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q And this Exhibit 91 is from</p> <p>21 PCPC-MDL-44971.</p> <p>22 Do you recognize that document?</p> <p>23 A I don't think so.</p> <p>24 Q Okay. It does appear to come from the</p> <p>25 PCPC files; is that right?</p>	<p>1 MR. LOCKE: I'd ask that the witness,</p> <p>2 since she has not seen the document before, be</p> <p>3 allowed to read the document, rather than just one</p> <p>4 or two bullet points.</p> <p>5 MR. MEADOWS: Okay. Well, if she wants</p> <p>6 to do that, we can take a little break and go to</p> <p>7 the restroom.</p> <p>8 MR. LOCKE: I don't want to take a</p> <p>9 break, but --</p> <p>10 MR. MEADOWS: I do. I got to go to the</p> <p>11 restroom.</p> <p>12 MR. LOCKE: Okay.</p> <p>13 THE VIDEOGRAPHER: All right. The time</p> <p>14 is 12:01 p.m. We're going off the record.</p> <p>15 (Recess.)</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 12:04 p m., and we're back on the record.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Okay. Dr. Loretz, did you get an</p> <p>20 opportunity to take a look at that document?</p> <p>21 A I did.</p> <p>22 Q Okay. So Dr. Katz -- I think we were</p> <p>23 talking about Dr. Katz, and you were telling us</p> <p>24 who she is.</p> <p>25 A Yes. She heads up OCAC.</p>

40 (Pages 916 to 919)

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<p>1 Q Okay. And she is -- I think she was</p> <p>2 referenced yesterday as being someone who worked</p> <p>3 for John Bailey.</p> <p>4 MR. LOCKE: Objection to form.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q Okay. She worked with John Bailey at</p> <p>7 the FDA.</p> <p>8 A Yeah, I think that was stated, and I</p> <p>9 said that I didn't know that she had worked for</p> <p>10 him. I knew she had worked at F- -- at FDA, but I</p> <p>11 just don't know.</p> <p>12 Q Okay. In any event, she -- after John</p> <p>13 Bailey left FDA, she became the head of Colors,</p> <p>14 right?</p> <p>15 A Of Cosmetics and Colors, yes.</p> <p>16 Q All right. And so Dr. Katz says -- or</p> <p>17 this says that Dr. Katz emphasized that she cannot</p> <p>18 carte blanche adopt CIR findings, right?</p> <p>19 A That's correct.</p> <p>20 Q "That would work only if FDA does the</p> <p>21 evaluation. For now she doesn't have the</p> <p>22 manpower. Further, the current process does not</p> <p>23 provide for FDA's review leading to adopt or not."</p> <p>24 Right?</p> <p>25 A Yes.</p>	<p>1 A Westine.</p> <p>2 Q -- Westine commented that PCPC is</p> <p>3 working with industry to obtain responses to FDA's</p> <p>4 questions. Follow-up, working with PCPC, the</p> <p>5 Industrial Minerals Association will contact FDA."</p> <p>6 Did I read that correctly?</p> <p>7 A You did.</p> <p>8 Q What was going on with respect to</p> <p>9 asbestos in 2009?</p> <p>10 MR. LOCKE: Objection. Asked and</p> <p>11 answered. Mr. Tisi covered this ground at length</p> <p>12 well over an hour yesterday.</p> <p>13 THE WITNESS: This would have to do with</p> <p>14 the meeting that was requested by Dr. John Bailey</p> <p>15 where we met with FDA, and then they had follow-up</p> <p>16 questions related to -- I guess composition of</p> <p>17 talc, and this is -- appears to be us responding</p> <p>18 to -- that we were working on responses for -- for</p> <p>19 FDA.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q What -- what prompted the concerns about</p> <p>22 FDA during this time period?</p> <p>23 MR. LOCKE: Objection. Asked and</p> <p>24 answered.</p> <p>25 BY MR. MEADOWS:</p>
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<p>1 Q So was there some discussion between FDA</p> <p>2 in this time period and PCPC about getting FDA to</p> <p>3 start adopting the CIR findings?</p> <p>4 A I think there has -- again, we -- "we"</p> <p>5 industry, PCPC or CTFA, started CIR because no one</p> <p>6 else was, and I think we've always had an interest</p> <p>7 in FDA, who does participate in the process as a</p> <p>8 liaison member, to be supportive of it.</p> <p>9 So then this -- I think this</p> <p>10 conversation looked like -- and their position has</p> <p>11 always been that we don't -- we won't carte</p> <p>12 blanche adopt them, opinions. And so I think this</p> <p>13 was a conversation around, is there something we</p> <p>14 can do to make you feel more comfortable with CIR</p> <p>15 conclusions, and -- I'm kind of done.</p> <p>16 Q Kind of done?</p> <p>17 A Yeah.</p> <p>18 Q Okay. I didn't want to cut you off.</p> <p>19 Okay. So staying on this document, and</p> <p>20 going over to the next page. Number 7, it's 2009,</p> <p>21 right?</p> <p>22 A Yes.</p> <p>23 Q "Information on asbestos in talc,"</p> <p>24 Dr. Katz raised this issue.</p> <p>25 Ms. Westin, is that --</p>	<p>1 Q Excuse me. Let me rephrase it.</p> <p>2 What prompted the concerns by FDA with</p> <p>3 respect to asbestos during this time period?</p> <p>4 MR. LOCKE: Objection. Asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: I'm not --</p> <p>7 MR. LOCKE: Discussed it at length</p> <p>8 yesterday.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q I'm sorry.</p> <p>11 A I mean, I don't know specifically. I --</p> <p>12 I mean, obviously we met with them and talked</p> <p>13 about this. But what -- what -- what prompted</p> <p>14 them, I don't know.</p> <p>15 Q Okay. All right.</p> <p>16 In any event, it appears that there was</p> <p>17 some efforts to respond to FDA inquiry in part by</p> <p>18 PCPC working with the Industrial Minerals</p> <p>19 Association; is that correct?</p> <p>20 A That's what it says.</p> <p>21 Q It's also known as IMA?</p> <p>22 A Correct.</p> <p>23 Q Okay. And IMA is a group -- well, you</p> <p>24 tell me, what is IMA?</p> <p>25 A They're a trade associate -- trade</p>

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<p>1 association representing industrial minerals, of 2 which talc would be one. 3 Q Okay. PCPC work with IMA on a regular 4 basis? 5 A I would say on an infrequent basis. 6 Q With respect to issues pertaining to 7 talc, does PCPC work with IMA on a regular basis? 8 A I would again say infrequent. This is 9 actually -- I don't think I was aware of this 10 reference here. I know that we were participating 11 on phone calls with them around the time of the 12 IARC review. So again, infrequent. 13 Q Okay. 14 (Exhibit No. 92 was marked for 15 identification.) 16 BY MR. MEADOWS: 17 Q All right. The next document I have is 18 Exhibit 92. And it is -- it is PCPC-MDL-6526, 19 correct? 20 A Correct. 21 Q Okay. And these are more minutes. 22 We -- I think we looked at some minutes a few 23 minutes ago. 24 A Correct, same committee. 25 Q And these are ones drafted by you.</p>	<p>1 general, and this was true with this committee. 2 We had -- we rotate the chairs every two years. 3 So this is when Tim was the chair. 4 Q Okay. So it's 2012, right? 5 A Yes. 6 Q It's the same year that talc is being 7 reviewed by the CIR, correct? 8 A Yes. 9 Q And Tim McCarthy with Johnson & Johnson 10 is the chair of the Safety and Regulatory 11 Toxicology Committee? 12 A Unrelated events, but yes. 13 Q If you flip over to -- the document is 14 not numbered. So if you go to Section 6, it looks 15 like. 16 A It's numbered -- the page number is on 17 the top. 18 Q Well, it doesn't have a Bates number on 19 it, doesn't it? 20 MR. LOCKE: And the numbers on the top. 21 BY MR. MEADOWS: 22 Q It's being whispered in my ear and 23 everybody -- everybody sees numbers but me. Sorry 24 about that. So page -- 25 A They're my minutes, so I know that.</p>
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<p>1 A Yes. 2 Q It looks like it was September of 2012 3 for a meeting held in D -- in Washington, D.C., 4 right? 5 A Yes. 6 Q A meeting of the Safety and Regulatory 7 Toxicology Committee, correct? 8 A Correct. 9 Q And at that meeting there were a number 10 representing various companies, correct? 11 A Yes. 12 Q Including Tim McCarthy from Johnson & 13 Johnson? 14 A Correct. 15 Q Okay. And then you were there, correct? 16 A Yes. 17 Q Okay. And then under "Opening Remarks," 18 A, "Chairman's Welcome." 19 A Mm-hmm. 20 Q Number 1, it says: "Tim McCarthy opened 21 the meeting and welcomed those present." 22 So I take it that Tim McCarthy was the 23 chairman at this time. 24 A Yes. And the way -- standing committees 25 work a little differently than task force in</p>	<p>1 Q -- page 7. Yeah, I didn't mean to 2 disparage your minutes. Sorry about that. 3 So page 7 of your minutes. 4 Subsection -- I guess it's vii. Isn't it Roman 5 numeral vii? 6 A Yes. 7 Q "Talc"? 8 A Yes. 9 Q "The SLR is posed, and talc is expected 10 to be on the December agenda." 11 A And that should say "posted," but yes. 12 Q Okay. Going over to the next page, 13 subparagraph ii at the top, it says: "The CIR SSC 14 continues to discuss improved metrics for CIR to 15 accurately reflect the value of the program. 16 Currently the number of ingredients reviewed is 17 being used as the primary measurement of CIR 18 value." 19 What's that all about? 20 A We -- PCPC faced a lot of criticism -- 21 or CIR faced a lot of criticism for not reviewing 22 enough ingredients, and that was part of the 23 reason that we -- the program got a little ramped 24 up. We added new people so that more reviews 25 could happen, as well as added more expertise, so</p>

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<p>1 that, just generally, to make the reviews perhaps</p> <p>2 more sophisticated.</p> <p>3 But there was -- previous to this, there</p> <p>4 wasn't the conscious effort to try to do more</p> <p>5 ingredients, so -- and again, we added the</p> <p>6 chemists. So the idea is you're grouping, but</p> <p>7 those groupings need to be appropriate. You can't</p> <p>8 group just to group. So to try to get more</p> <p>9 ingredients through the program.</p> <p>10 Q So let me make sure I understand</p> <p>11 correctly.</p> <p>12 There was criticism in 2012 that the --</p> <p>13 that there weren't being enough ingredients</p> <p>14 reviewed?</p> <p>15 A Correct. I mean, we would get criticism</p> <p>16 that, you know, how valuable is CIR if they</p> <p>17 haven't reviewed enough ingredients. But again,</p> <p>18 it is to group ingredients that belong together.</p> <p>19 But in previous years there wasn't necessarily any</p> <p>20 push to do that, so then you didn't have the kind</p> <p>21 of grouping. All -- all -- none relevant to talc,</p> <p>22 but...</p> <p>23 Q Who was -- who was criticizing that CIR</p> <p>24 was not reviewing enough ingredients in 2012?</p> <p>25 A We were being criticized, kind of the</p>	<p>1 A Which specific NGO?</p> <p>2 Q Yeah, who was the most vocal NGO to say</p> <p>3 that CIR is not reviewing enough ingredients?</p> <p>4 A I mean, I can tell you a couple of vocal</p> <p>5 CEOs -- excuse me, CEOs -- local NGOs, but I'm not</p> <p>6 sure that that would necessarily correspond to</p> <p>7 who exact -- which NGOs, but it was a frequent</p> <p>8 criticism. Public criticism.</p> <p>9 Q Okay. But by frequent, I mean --</p> <p>10 A Well --</p> <p>11 Q -- who was the most vocal?</p> <p>12 A I would guess the cosmetic -- I'm not</p> <p>13 sure. I'm really not sure.</p> <p>14 Q Okay. But can you tell --</p> <p>15 A We get criticized for various things.</p> <p>16 Q Can you give me an example of who was</p> <p>17 vocal about CIR not reviewing enough ingredients?</p> <p>18 A I mean, I can give you an example of an</p> <p>19 NGO that's very critical.</p> <p>20 Q Great.</p> <p>21 A Cosmetics for -- Campaign for Safe</p> <p>22 Cosmetics.</p> <p>23 Q Campaign for Safe Cosmetics. They were</p> <p>24 critical of CIR for not reviewing enough --</p> <p>25 A No, that's what I'm saying. I mean, I</p>
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<p>1 CIR program as a whole, by outside groups that CIR</p> <p>2 has only reviewed X many ingredients, and yet</p> <p>3 there's this many in our cosmetic dictionary.</p> <p>4 Q I heard that. What I want to know is,</p> <p>5 who was critical of --</p> <p>6 A Which specific --</p> <p>7 Q -- of CIR not reviewing enough</p> <p>8 ingredients.</p> <p>9 A It was -- I mean, outside NGOs.</p> <p>10 Q Non-governmental organizations were</p> <p>11 criticizing CIR for not reviewing enough</p> <p>12 ingredients on an annual basis?</p> <p>13 A No, not -- for overall CIR not having</p> <p>14 only reviewed X many ingredients, and yet there's</p> <p>15 this many ingredients used in cosmetics. We were</p> <p>16 being criticized for saying our ingredients --</p> <p>17 that we're using unreviewed ingredients.</p> <p>18 And that's -- that's not the way the</p> <p>19 industry goes. I mean, again, the first -- I</p> <p>20 mean, there's an obligation by law that your</p> <p>21 product has to be safe to put out on the market,</p> <p>22 so those ingredients are reviewed but not in a</p> <p>23 public forum with a CIR report.</p> <p>24 So that's where the criticism came from.</p> <p>25 Q Okay. But I'm more interested in who.</p>	<p>1 know we were criticized frequently. I can't</p> <p>2 correspond an exact NGO to that criticism, but</p> <p>3 that was a frequent criticism.</p> <p>4 Q Okay. So you're saying that generally</p> <p>5 NGOs were criticizing CIR for not reviewing enough</p> <p>6 ingredients, but you can't remember in particular</p> <p>7 which NGOs those were.</p> <p>8 A CIR was frequently criticized for that,</p> <p>9 yes.</p> <p>10 Q Can you recall which NGOs --</p> <p>11 A No.</p> <p>12 Q -- were critical in that regard?</p> <p>13 A No.</p> <p>14 Q Back to the first page. I'm curious as</p> <p>15 to why this committee meeting was held at the</p> <p>16 offices of Covington & Burling. It's a law firm,</p> <p>17 isn't it?</p> <p>18 A Yeah. I mean, the simple answer is they</p> <p>19 have meeting space, and we -- they used to -- we</p> <p>20 used to meet there -- we do business with them,</p> <p>21 and we hire them for various things, and they</p> <p>22 would allow us to use their meeting space. We</p> <p>23 didn't have a big enough conference room in our</p> <p>24 offices.</p> <p>25 Q Okay. All right. I'll show you what</p>

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<p>1 we've marked as Exhibit 93. 2 (Exhibit No. 93 was marked for 3 identification.) 4 BY MR. MEADOWS: 5 Q And it's Bates-stamped PCPC-MDL-875, 6 correct? 7 A Yes. 8 Q Okay. And it's entitled "Personal Care 9 Products Council, Council Executive Committee 10 Meeting Agenda," held at the Ritz Carlton here in 11 D.C., correct? 12 A Yes. 13 Q On June 2013. 14 A Yes. 15 Q Were you at this? 16 A No. 17 Q Okay. Who would have attended this? Is 18 it reflected on here? Maybe it is. 19 A Yeah, I would assume it is. I mean, I 20 see three on the front, but... 21 Q Okay. Flipping over to the third page. 22 It says: "Primary issues in the negotiations." 23 What -- what negotiations are we talking 24 about here, do you know? 25 A So just to make sure, but it looks like</p>	<p>1 widely used. 2 Q So this is a process by which companies 3 would voluntarily report what ingredients they're 4 using in their products. 5 A Correct. 6 Q And they would report that to the FDA. 7 A Correct. 8 Q Is that currently going on or -- 9 A Yes. 10 Q Okay. All right. On the second 11 proposal, they have rejected the process for 12 petition -- petitioning ingredients for review and 13 the concept of a review and approval of all CIR 14 findings. 15 So that concept is floating once again 16 about FDA approving CIR findings, right? 17 A Yes. 18 MR. LOCKE: Objection. Form. 19 BY MR. MEADOWS: 20 Q Is that -- 21 A Related to CIR findings, yes. 22 Q So industry -- 23 A So it -- so it appears. 24 Q So industry wanted -- we saw a document 25 earlier, I think it was from 2009, right, where</p>
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<p>1 this is talking about federal legislation, and 2 that's been something that -- I guess I would have 3 to go back, though. It talks about negotiation 4 with FDA. But we've been involved with trying to 5 have a new federal legislation now for quite a few 6 years. 7 Q All right. So this says: "FDA has 8 essentially agreed to the first proposal agreeing 9 to make the FDA voluntary reporting program 10 mandatory." 11 Do you -- are you familiar with that? 12 A No. One second, but -- (peruses 13 document.) Okay. Yes. 14 Q All right. You are familiar with that? 15 A Yes. 16 Q Okay. What is that all about? 17 A It is about FDA has a program where you 18 report use of ingredients, and then they -- 19 basically you're reporting -- well, the ingredient 20 and the product type, and FDA has certain product 21 type categories. And that is part of the 22 information that -- that CIR uses in prioritizing 23 ingredients too, because it's good for knowing 24 kind of at least a good general sense, although 25 it's a voluntary program of what ingredients are</p>	<p>1 industry appeared to be wanting the FDA to approve 2 CIR findings, and that was rejected, right? Linda 3 Katz? 4 A Right, right. As I say, we've always 5 wanted greater recognition by FDA of CIR and how 6 we could make that happen. 7 Q So in 2013 there is another attempt to 8 get FDA to -- to review and approve all CIR 9 findings, correct? 10 A Well, I think -- I mean, this is part of 11 the whole federal legislation, which encompasses 12 all kinds of things such as the voluntary 13 reporting program, GMPs, et cetera, and part of 14 that is ingredient safety, and, you know, what -- 15 would FDA do reviews. You know, could CIR be used 16 in some way in that process. So I think that was 17 all discussions that went on. 18 Q Okay. But even in 2013, the FDA is 19 still not willing to, in the words of Linda Katz, 20 carte blanche approve all CIR findings. 21 A They've always -- 22 MR. LOCKE: Objection to form. 23 THE WITNESS: They've always taken that 24 position, yes. 25 BY MR. MEADOWS:</p>

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<p>1 Q All right. Going down to the last 2 section, "Safety Standard." 3 It says: "The Lance bill had a safety 4 standard that would apply throughout the federal 5 statute on cosmetics." 6 Are you familiar with this? 7 A Not specifically what the Lance bill 8 said. There have been all kind of bills over the 9 years, but I -- I'm aware that safety standard has 10 been one issue of the federal legislation. 11 Q So we talked a lot about the definition 12 of "safety" this morning, right? 13 A We talked about what the CIR uses as 14 their definition, yes. 15 Q Correct. And then we talked about the 16 standard used in the Code of Federal Regulations 17 to -- to trigger a warning, right? 18 MR. LOCKE: Objection to form. 19 THE WITNESS: We talked about the words 20 that were used in the federal reg, yes. 21 BY MR. MEADOWS: 22 Q This goes on to FDA -- to say: "FDA has 23 rejected the standard because they consider it too 24 easy to satisfy given the relatively low societal 25 value of cosmetics."</p>	<p>1 here. Again, there have been other bills with 2 other safety standards. That's always been a 3 negotiation point of the words and what they mean 4 and -- so... 5 BY MR. MEADOWS: 6 Q And the concept that the -- that 7 cosmetics have a relatively low societal value is 8 what prompts us to want to make sure that a 9 cosmetic is safe before it's exposed to the 10 public, correct? 11 MR. LOCKE: Objection to form and beyond 12 the scope. 13 THE WITNESS: Can you repeat the 14 question? 15 BY MR. MEADOWS: 16 Q Well, the concept that cosmetics have a 17 low societal value are the reason why we want to 18 make sure that cosmetics are safe before they're 19 exposed to the public. 20 MR. LOCKE: Same objections. 21 THE WITNESS: I think we want to make 22 sure cosmetics are safe before they go to the 23 public because they should be safe. That's what 24 the law says. 25 BY MR. MEADOWS:</p>
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<p>1 Did I read that correctly? 2 A That's what it says, yes. 3 Q So what -- do you know anything about 4 this standard that -- I assume the industry was 5 behind the Lance bill. Is that -- 6 MR. LOCKE: Objection -- 7 BY MR. MEADOWS: 8 Q -- fair to say? 9 MR. LOCKE: Objection to form and beyond 10 the scope. 11 THE WITNESS: I -- I actually don't 12 know. 13 BY MR. MEADOWS: 14 Q Don't know. Okay. 15 A I mean, again, there's, you know, so 16 much legislation activity and various bills where 17 we might be behind some, others are still being 18 negotiated. So I can't make a broad statement. 19 Q Okay. In any event, FDA is concerned 20 about having too low a bar when it comes to 21 cosmetics because, frankly, cosmetics, in their 22 words, have a relatively low societal value, 23 right? 24 MR. LOCKE: Objection to form. 25 THE WITNESS: I mean, that's the words</p>	<p>1 Q Yeah. 2 A I mean -- 3 Q And it's why we have -- it's why 4 cosmetics have a low bar when it comes to safety 5 as compared to pharmaceuticals, right? 6 MR. LOCKE: Objection to form, beyond 7 the scope. 8 THE WITNESS: Pharmaceuticals 9 and cosmetics are -- 10 THE REPORTER: I'm sorry, 11 pharmaceuticals and? 12 THE WITNESS: Cosmetics and 13 pharmaceuticals, I mean, are -- are different. 14 That's kind of an apples to oranges -- 15 BY MR. MEADOWS: 16 Q Yeah. I think yesterday you were 17 talking in terms of efficacy, right? 18 A Of activity, yeah. 19 Q Mm-hmm. So there is cosmetics -- 20 because there is no usefulness or they have a low 21 societal value, as stated here, you've got to have 22 a pretty high standard when it comes to safety, 23 right? 24 MR. LOCKE: Objection to form and beyond 25 the scope.</p>

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<p>1 THE WITNESS: I mean, I think, again, I</p> <p>2 would just say that people are being exposed to</p> <p>3 them, they should be safe.</p> <p>4 Pharmaceuticals are different in the</p> <p>5 sense that they are designed to have biological</p> <p>6 activity, so it changes the evaluation. But both</p> <p>7 need to be safe.</p> <p>8 MR. MEADOWS: Tom, I'm going to follow</p> <p>9 your lead on lunch. I don't know what y'all have</p> <p>10 planned, so you just -- you just let me know when</p> <p>11 you're -- when you're ready to do that.</p> <p>12 MR. LOCKE: Well, since we just took a</p> <p>13 break, why don't we keep going for a little bit</p> <p>14 more.</p> <p>15 MR. MEADOWS: Okay.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q All right. We've talked some, and I</p> <p>18 think you have indicated that -- well, let's talk</p> <p>19 about this first.</p> <p>20 Let me ask you about this document.</p> <p>21 This is Exhibit 94.</p> <p>22 (Exhibit No. 94 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q And I'm not going to ask you about the</p>	<p>1 Q And this was sent October 2012, which</p> <p>2 was the year that talc was being reviewed by the</p> <p>3 CIR, correct?</p> <p>4 A Correct.</p> <p>5 Q Okay. What -- what is the purpose of</p> <p>6 this document? Can you tell me why it was sent?</p> <p>7 A When the CIR releases a scientific</p> <p>8 literature review, which is the first thing the</p> <p>9 public sees, and that's their -- that's their</p> <p>10 document coming out. Before then you might know</p> <p>11 they're planning to review something, but this is</p> <p>12 the first document you see.</p> <p>13 And the Council Science department</p> <p>14 reviews -- actually, it's my co-worker, Carol</p> <p>15 Eisenmann takes the lead, reviews the scientific</p> <p>16 literature review, and provides comments that are</p> <p>17 kind of content. Perhaps a paper is missing that</p> <p>18 seems obvious. Tend to be editorial -- or I don't</p> <p>19 know if you call it editorial, but this study</p> <p>20 should really more appropriately belong in this</p> <p>21 section, not where it is. Those kind of</p> <p>22 comments -- I believe on every scientific</p> <p>23 literature review she has comments because that's</p> <p>24 the first time it's coming through, and so there</p> <p>25 are those kind of comments.</p>
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<p>1 specifics of the document.</p> <p>2 A Okay.</p> <p>3 Q I just want to know what it is.</p> <p>4 A Okay.</p> <p>5 Q Okay? So we marked it as 94, and it's</p> <p>6 Bates PCPC-MDL-2908.</p> <p>7 A Yes.</p> <p>8 Q Personal Care Products Council</p> <p>9 letterhead, correct?</p> <p>10 A Correct.</p> <p>11 Q And it's a memorandum, right?</p> <p>12 A Yes.</p> <p>13 Q To Alan Andersen. We talked about</p> <p>14 Dr. Andersen earlier, correct?</p> <p>15 A Correct.</p> <p>16 Q He was the director of the Cosmetic</p> <p>17 Ingredient Review, correct?</p> <p>18 A That's correct.</p> <p>19 Q And so this memo is going to him at the</p> <p>20 CIR, and it's coming from -- can you pronounce</p> <p>21 that person's name?</p> <p>22 A Halyna Breslawec.</p> <p>23 Q Okay. And this person is the industry</p> <p>24 liaison to the CIR expert panel, correct?</p> <p>25 A Correct.</p>	<p>1 Q Okay. So this is -- this is normal</p> <p>2 for --</p> <p>3 A It is normal for all reports, yes.</p> <p>4 Q So it's normal to see that a memo would</p> <p>5 be coming from the industry liaison to the CIR</p> <p>6 expert panel to the director of the CIR on PCPC</p> <p>7 letterhead.</p> <p>8 A Yes.</p> <p>9 Q Okay. Now, we've talked about the CIR</p> <p>10 being transparent, right? That was your word.</p> <p>11 A Open, I think is --</p> <p>12 Q Okay. And we talked about -- we talked</p> <p>13 a few minutes ago about how the -- those who do</p> <p>14 the reviews don't have the benefit of doing -- of</p> <p>15 having discussions in private in order to</p> <p>16 challenge information that's being provided,</p> <p>17 correct?</p> <p>18 A They can --</p> <p>19 MR. LOCKE: Objection to form.</p> <p>20 THE WITNESS: They can challenge</p> <p>21 information, but they don't have a private</p> <p>22 meeting, that's correct.</p> <p>23 (Exhibit No. 95 was marked for</p> <p>24 identification.)</p> <p>25 BY MR. MEADOWS:</p>

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<p style="text-align: right;">Page 944</p> <p>1 Q All right. I show you what I've marked 2 as Exhibit 95. 3 Now, this document comes from the Imerys 4 files, you'll see. 5 A Okay. 6 Q It's Imerys Bates -- plaintiff -- it 7 says Pltf_IMERYYS 17841 is the bottom number there. 8 And some of this -- it's an e-mail 9 string as you can see. 10 A Yep. 11 Q Some of it you are not on, as far as I 12 can tell, but it appears that the first e-mail -- 13 and when I say "you," I mean PCPC. 14 A Okay. 15 Q It appears that the first e-mail at 16 least was between Tim McCarthy and Carol 17 Eisenmann. Am I correct about that? 18 A Yes. 19 Q And so that's what I want to focus on, 20 and I -- maybe it's there. I couldn't find this 21 in -- in the documents that were provided by PCPC. 22 But that's why I'm using the Imerys version, okay? 23 A Okay. 24 Q All right. So it appears this is an 25 e-mail -- let's zero in on this a little bit,</p>	<p style="text-align: right;">Page 946</p> <p>1 A You did. 2 Q Now, why is it appropriate for the 3 expert panel to not have the benefit of private 4 conversations, but it's okay for the company that 5 has an interest in the ingredient and the result 6 of this review to have anonymity on what they're 7 submitting to the panel? 8 MS. FRAZIER: Object to form. 9 MR. LOCKE: Objection to form and beyond 10 the scope. 11 THE WITNESS: I mean, I guess I would 12 just say that -- that these comments -- comments 13 go to the expert panel. They can take them or 14 leave them, judge them on their merit. This is 15 specifically on the topic of damaged skin barrier. 16 BY MR. MEADOWS: 17 Q And do you think it's not important for 18 the -- if there's going to be an open -- open and 19 transparent forum, as you describe it, that the 20 panel have the benefit of knowing where 21 information is coming from? 22 MR. LOCKE: Objection to form. 23 THE WITNESS: I think it's the value of 24 the information. If -- I mean, I don't know what 25 this looks like. It's apparently addressing the</p>
<p style="text-align: right;">Page 945</p> <p>1 okay -- from Tim McCarthy sent February 28, 2013, 2 correct? 3 A Yes. 4 Q To -- is it pronounced Carol Eisenmann? 5 A Correct. 6 Q Okay. And then it has a few folks 7 copied at J&J, correct? 8 A Yes. 9 Q Tim McCarthy is at J&J. Correct? 10 A Correct. 11 Q "Subject: Talc, CIR final draft." 12 Did I read that correctly? 13 A Yes. 14 Q Okay. And it says: "Carol, hello. Per 15 our conversation, enclosed you will find our 16 comments regarding the current talc SLR text 17 specific -- specifically on the topic of damaged 18 skin barrier. The cover letter from me to you. 19 The comments to the expert panel are in a separate 20 document. We wish that these comments be 21 delivered to the expert panel on behalf of a 22 councilmember without attribution back to J&J. If 23 you have any questions, please feel free to 24 contact me. Regards, Tim." 25 Did I read that correctly?</p>	<p style="text-align: right;">Page 947</p> <p>1 topic of damaged skin barrier, if it's 2 appropriately referenced. I -- it's -- I think, 3 you know, if it's based on published literature, I 4 think the panel can judge if it's valuable 5 information or not. 6 BY MR. MEADOWS: 7 Q So where it's coming from makes no 8 difference? 9 A I -- 10 MR. LOCKE: Objection to form and beyond 11 the scope. 12 THE WITNESS: I mean, if -- yeah, if 13 it's published information, where it's coming from 14 is the people who publish -- the scientists who 15 publish that information. 16 BY MR. MEADOWS: 17 Q Well, obviously it made a difference to 18 J&J, right? They did not -- they didn't want the 19 panel to know where this information was coming 20 from, right? 21 MS. FRAZIER: Objection to form. 22 MR. LOCKE: Objection to form. 23 THE WITNESS: I mean, I -- as I say, I 24 think you need to judge the comments, which I 25 can't see, but on the basis of the information.</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q Yeah, I'm not talking about the</p> <p>3 substance of the comments. I'm talking about the</p> <p>4 process. We've been talking about process, and</p> <p>5 you've said that the CIR is an open and trans- --</p> <p>6 I remember the word "transparent" at some point in</p> <p>7 time -- process.</p> <p>8 And I've questioned on whether or not</p> <p>9 that's really good for a reviewer who is being</p> <p>10 paid by the person who is -- wants their product</p> <p>11 deemed safe, and whether or not that reviewer can</p> <p>12 have an open and honest discussion about the</p> <p>13 safety of that ingredient knowing that the people</p> <p>14 who are paying them are watching.</p> <p>15 And you've said, Well, that's just part</p> <p>16 of the process, it's open and transparent. Right?</p> <p>17 A It would --</p> <p>18 MS. FRAZIER: Object to form.</p> <p>19 MR. LOCKE: Objection. Form.</p> <p>20 THE WITNESS: It would be --</p> <p>21 MR. LOCKE: Compound.</p> <p>22 THE WITNESS: It would be clear this is</p> <p>23 coming from industry. That's not -- and what</p> <p>24 you've been saying is industry is paying for them.</p> <p>25 It's clear this comes from industry.</p>	<p>1 Q Right. And -- but the money that's</p> <p>2 coming from J&J dwarfs what everybody else is</p> <p>3 contributing to PCPC, doesn't it?</p> <p>4 MR. LOCKE: That is false. You know</p> <p>5 it's false if you've read Mr. Pollack's deposition</p> <p>6 testimony.</p> <p>7 MS. FRAZIER: And object to form.</p> <p>8 THE WITNESS: No, that's -- yeah, that's</p> <p>9 not correct.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Okay. Well, if J&J said, Let them know</p> <p>12 it's coming from us, then we could call this an</p> <p>13 open and transparent process, couldn't we?</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: I -- I think I would just</p> <p>16 say it's known that this is coming from industry.</p> <p>17 Companies can submit on their own, they could</p> <p>18 submit through PCPC.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q But what's not known is that it's coming</p> <p>21 from the company that has the biggest interest in</p> <p>22 what's at stake with respect to talc, correct?</p> <p>23 MS. FRAZIER: Objection to form.</p> <p>24 MR. LOCKE: Objection. And asked and</p> <p>25 answered.</p>
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<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. What's not clear is it is coming</p> <p>3 from J&J, right?</p> <p>4 MR. LOCKE: Objection to form.</p> <p>5 THE WITNESS: It's coming from industry,</p> <p>6 and the comments can be assessed based on their</p> <p>7 scientific value. But it is clear it's coming</p> <p>8 from industry.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q It's clear that there's no way this --</p> <p>11 this panel is going to know that it's coming from</p> <p>12 J&J, right?</p> <p>13 A Yes.</p> <p>14 Q Okay. And J&J, they're the principal</p> <p>15 funder of -- of the PCPC, aren't they?</p> <p>16 MR. LOCKE: Objection. Asked and</p> <p>17 answered with respect to Mark Pollack, corporate</p> <p>18 representative deposition testimony, and</p> <p>19 mischaracterization.</p> <p>20 MS. FRAZIER: Object to form.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q Am I correct?</p> <p>23 A PCPC funds CIR, and it would -- these</p> <p>24 comments would be coming from PCPC. So that much</p> <p>25 is evident.</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Correct?</p> <p>3 MR. LOCKE: Asked and answered. She's</p> <p>4 already answered that question.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q Correct?</p> <p>7 MR. LOCKE: Not -- don't answer it</p> <p>8 again.</p> <p>9 MR. MEADOWS: All right. I'm at a good</p> <p>10 breaking point.</p> <p>11 THE VIDEOGRAPHER: The time is 12:40</p> <p>12 p.m. We're going off the record.</p> <p>13 (Lunch recess.)</p> <p>14 THE VIDEOGRAPHER: The time is</p> <p>15 1:15 p m., and we're back on the record.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q All right. Dr. Loretz, next, I would</p> <p>18 like to turn to -- we talked a little bit about</p> <p>19 this, but I want to talk a little bit more about</p> <p>20 it, and that is the -- the process -- the CIR talc</p> <p>21 process, people involved, and how it was funded,</p> <p>22 and just some of the interactions that took place.</p> <p>23 The first question I have, though, is to</p> <p>24 what extent was the -- the PCPC staff involved in</p> <p>25 the review -- the CIR review of talc?</p>

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<p>1 A Same as any other report. So we don't</p> <p>2 see anything until the scientific literature</p> <p>3 review comes out. And then we would see</p> <p>4 reports -- and then we do attend the -- the CIR</p> <p>5 meetings.</p> <p>6 So as I've said before, how -- there's a</p> <p>7 chance to talk after the expert panel talks. It's</p> <p>8 true for the public. It would be true for CIR</p> <p>9 staff, and of course, there's the -- I'm sorry,</p> <p>10 CIR staff -- PCPC staff. The liaison, of course,</p> <p>11 is there as we've discussed. So that would be the</p> <p>12 normal process one could talk at that point.</p> <p>13 But CIR -- we don't see the report until</p> <p>14 the scientific literature review comes out, and</p> <p>15 then the -- after the expert panel gives their</p> <p>16 input to staff, to CIR staff, CIR staff goes back</p> <p>17 and takes the report to the next step. And again,</p> <p>18 we wouldn't see it during that process. We would</p> <p>19 see it when the next report comes out.</p> <p>20 Q And so is PCPC at all involved in the</p> <p>21 editing of -- of the report?</p> <p>22 A Only -- no. But we do submit comments,</p> <p>23 as you just saw, for the scientific literature</p> <p>24 review for consideration by CIR staff, and then,</p> <p>25 of course, in the report, the expert panel has the</p>	<p>1 show this -- well, she probably needs to be</p> <p>2 involved in that.</p> <p>3 While she's looking, I want to make sure</p> <p>4 I understand how to pronounce her name. Is it</p> <p>5 Fumay (phonetic)?</p> <p>6 A You're probably asking the wrong person.</p> <p>7 That's probably how I would say it, but I'm</p> <p>8 actually not certain.</p> <p>9 Q Well, do you know her?</p> <p>10 A Oh, yeah, Monice, yes.</p> <p>11 Q Okay. So let's see.</p> <p>12 (Counsel conferring.)</p> <p>13 MR. MEADOWS: Tell you what, we can mark</p> <p>14 it later. I'm just going to -- I'm going to show</p> <p>15 her the list so we're all on the same page here.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q All right. Dr. Loretz, I've got up on</p> <p>18 the screen --</p> <p>19 A That's fine.</p> <p>20 Q -- the Safety Assessment of Talc As</p> <p>21 Used, the CIR article, as I would call it.</p> <p>22 A Okay.</p> <p>23 Q Okay. And then we've got this group of</p> <p>24 names up here.</p> <p>25 Monice, I believe?</p>
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<p>1 ultimate say of what the report should -- should</p> <p>2 look like.</p> <p>3 Q All right. Turn -- turning to the</p> <p>4 report itself -- and I don't have it in front of</p> <p>5 me right now, and if I have to pull it out, I</p> <p>6 will, but going on recollection, I want to ask you</p> <p>7 a question.</p> <p>8 My recollection is that there are -- I</p> <p>9 think it's 12 people listed as, I guess, authored</p> <p>10 the report or were involved in the panel.</p> <p>11 Is that -- is my memory correct, or do</p> <p>12 we need to get that thing out and take a look at</p> <p>13 it?</p> <p>14 A Well, the panel -- I mean, the panel</p> <p>15 would be eight -- there's eight, not counting the</p> <p>16 liaison members who would not be on that.</p> <p>17 Q Okay.</p> <p>18 A And then I'm not sure who is listed as</p> <p>19 an author from the CIR staff.</p> <p>20 Q Okay. All right.</p> <p>21 MR. MEADOWS: I probably need to look at</p> <p>22 it just to make sure I'm talking about the right</p> <p>23 name here.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q While she's pulling that out, I want to</p>	<p>1 A Yes.</p> <p>2 Q -- Fiume or -- okay. Ivan Boyer, Wilma</p> <p>3 Bergfeld, Donald Belsito, Ronald Hill, Curtis</p> <p>4 Klaassen, Daniel Liebler, James Marks, Ronald</p> <p>5 Shank, Thomas Slaga, Paul Snyder, and Alan</p> <p>6 Andersen.</p> <p>7 Have I read those correctly?</p> <p>8 A You did.</p> <p>9 Q And so I count that as 12 names listed</p> <p>10 as authors of this article, correct?</p> <p>11 A Yes.</p> <p>12 Q And would all 12 of those people, were</p> <p>13 they on -- were they the expert panel?</p> <p>14 A No. I misspoke when I said there were</p> <p>15 eight expert panel. There's nine because there's</p> <p>16 the chairman, which was Wilma Bergfeld. So nine</p> <p>17 of those people are expert panel members. Alan</p> <p>18 Andersen is the director of CIR, and Monice Fiume</p> <p>19 and Ivan Boyer are -- work for CIR.</p> <p>20 Q Okay. So Andersen, Fiume, and Boyer are</p> <p>21 employees of CI -- of CIR?</p> <p>22 A Correct.</p> <p>23 Q Employees of PCPC?</p> <p>24 A We -- yes, we pay for CIR, so yes.</p> <p>25 Q Okay. All right. The remainder -- the</p>

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<p>1 remaining nine are -- I guess, what do you call 2 them, consultants or scientific consultants or 3 what? 4 A Expert panel members, and, yes, they are 5 consultants. 6 Q Okay. They are not employees of either 7 CIR or PCPC. 8 A That is correct. 9 Q Okay. All right. The next document I 10 want to show you and we're going to mark is 11 Exhibit 96. 12 (Exhibit No. 96 was marked for 13 identification.) 14 BY MR. MEADOWS: 15 Q And you will see I marked it as 16 Exhibit 96, and it's Bates No. PCPC_MDL_145273, 17 correct? 18 A Yes. 19 Q Okay. And it appears to be a printout 20 from PCPC's -- entitled "Detailed Trial Balance 21 for 2002 General Ledger." 22 Did I read that correctly? 23 A Yes. 24 Q And it appears that it was printed out 25 earlier in this calendar year of 2018, correct?</p>	<p>1 A I have to go all through each page, 2 but -- 3 Q Yeah. 4 A -- that's what it appears to be, yes. 5 Q Okay. In any event, PCPC reimburses the 6 panel members for expenses, correct? 7 A Yes. 8 Q Okay. So, for instance, travel 9 expenses, flights, food, whatever is related -- 10 A Hotels, sure. 11 Q -- whatever is related to them having to 12 travel, hotel, PCPC reimburses the panel members 13 for their expenses. 14 A Yes. 15 Q Okay. And again, that's money that's 16 come from your members, your industry members, 17 correct? 18 A It's money from PCPC, yes. 19 Q All right. The next document would be 20 Exhibit 97. 21 (Exhibit No. 97 was marked for 22 identification.) 23 BY MR. MEADOWS: 24 Q And Exhibit 97 is Bates-stamped 25 PCPC_MDL_145326, correct?</p>
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<p>1 A Yes. 2 Q Okay. And it appears to be -- let's see 3 here. 4 Well, you tell me, do you know what this 5 is? 6 A I mean, it relates to expenses for 7 expert panel members. 8 Q Okay. So this would be -- this would 9 show reimbursements for expenses by members of 10 expert panels? 11 A I would assume that's what it is, yes. 12 Q Okay. And it appears to start in 2002. 13 Let's see -- if we go back up here at 14 the top, it says "Ranges, Date, January 1, 2002, 15 to December 31, 2002." I guess that's for the 16 first two pages. 17 MR. LOCKE: Yeah, for the record, this 18 is something Mr. Pollack was designated to 19 testify. I can't remember whether he did or not, 20 but it's beyond the scope of what this witness 21 would know. 22 BY MR. MEADOWS: 23 Q All right. And then it appears that as 24 you go, it goes to the next year, 2003, and then 25 2004, all the way up to, I guess, 2018, right?</p>	<p>1 A Yes. 2 Q Okay. And it too appears to be a ledger 3 printed out earlier in this calendar year, and 4 similarly, it has a date range starting on the 5 first page of 1/1/2002 to 12/31/2002, and then it 6 appears that it shows a ledger for each calendar 7 year, 2003, 2004, 2005, all the way up to 2018, 8 correct? 9 A That's what it looks like. 10 Q So 2012 was the year that talc was 11 considered, correct? 12 A I think it was not totally completed 13 that year, but that was one of the years when I 14 know they met on that, yes. 15 Q And just looking at Bates-stamped page 16 ending in 346. 17 A Okay. 18 Q And it appears that if you look over 19 Bates -- Bates page 347 -- well, first of all, 20 let's look at this. 21 This list of names on here, from my 22 look, appears to reflect the nine names that we 23 just talked about; is that correct? 24 A Unless -- 25 MR. LOCKE: Objection. Beyond the</p>

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<p>1 scope. This was a topic that Mr. Pollack was 2 designated to testify about. 3 THE WITNESS: I'll just say I also see 4 the Consumer Federation of America is on here as 5 well in addition to the nine. 6 BY MR. MEADOWS: 7 Q Okay. I tell you what, let's do this. 8 So going through this document, we've 9 got James Marks, right? He's the first one on 10 there, right -- correct? 11 A Yes. 12 Q And he is listed as an author, correct? 13 A Yes. 14 Q Daniel Liebler, he's listed as an 15 author, correct? 16 A Yes. 17 Q Thomas Slaga, he's listed as an author, 18 correct? 19 A Yes. 20 Q Ronald Shank, listed as an author, 21 correct? 22 A Correct. 23 Q Wilma Bergfeld, listed as an author, 24 correct? 25 A She's the chair, yes.</p>	<p>1 be, yes. 2 BY MR. MEADOWS: 3 Q And we do not see the names Monice 4 Fiume, Ivan Boyer or Alan Andersen on this list, 5 do we? 6 A Correct. They're employees of CIR. 7 Q Okay. And just looking at it, it 8 appears that there are amounts that are paid to 9 these experts in varying amounts paid to these 10 experts throughout the year of 2012, correct? 11 MR. LOCKE: Objection. Beyond the 12 scope. 13 THE WITNESS: That's what it appears to 14 be, yes. 15 BY MR. MEADOWS: 16 Q Okay. And there are -- and it appears 17 that they are paid on a quarterly basis? 18 MR. LOCKE: Objection. Beyond the 19 scope. 20 THE WITNESS: Because there are four 21 meetings a year, I would assume. 22 BY MR. MEADOWS: 23 Q Four meetings a year. Okay. 24 And it appears that this group ends up 25 being paid a total of -- well, including -- this</p>
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<p>1 Q Donald Belsito -- 2 A Yes. 3 Q -- listed as an author. 4 Ron Hill, listed as an author. 5 A That's correct. 6 Q Paul Snyder, listed as an author, 7 correct? 8 A Yes. 9 Q Then we've got the Consumer Federation. 10 Is there a particular name that would go 11 with the Consumer Federation or is that just -- 12 A They're a -- they're a liaison, so 13 they're not -- they would not author. 14 Q Okay. And then we've got Curtis 15 Klaassen listed as an author, correct? 16 A Yes. 17 Q All right. So this ledger reflects 18 payments made to these nine authors for their 19 services in the year of 2012, correct? 20 A Yes. 21 MR. LOCKE: Objection. Beyond the 22 scope, for Mr. Pollack's testimony. 23 You can answer in your personal 24 capacity. 25 THE WITNESS: That's what it appears to</p>	<p>1 would include the Consumer Federation, they were 2 paid a total of \$272,390 in 2012; is that correct? 3 MR. LOCKE: Objection. Beyond the 4 scope. 5 You can answer in your personal capacity 6 if you know. 7 THE WITNESS: I mean, that's what it 8 looks like. I mean, these are high -- highly 9 regarded professionals. 10 BY MR. MEADOWS: 11 Q Okay. Now, by my calculations from 12 looking at this, and excluding -- excluding the 13 Consumer Federation from the list, adding up 14 everything that we just looked at for 2012, what 15 I'm showing is that that committee of authors in 16 2012 was paid a total of \$247,490 in 2012 for 17 their services as expert panel members, correct? 18 MR. LOCKE: Objection. Beyond the 19 scope. Mr. Pollack was designated to testify on 20 this topic. 21 You can answer in your personal capacity 22 if you know. 23 THE WITNESS: I mean, I can only say 24 that's what it looks like. 25 BY MR. MEADOWS:</p>

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<p>1 Q No reason to dispute my number here?</p> <p>2 MR. LOCKE: Same objection and to form.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q And it's -- it's less than what is</p> <p>5 listed on the ledger, and I've removed the</p> <p>6 Consumer Federation amount.</p> <p>7 A Right.</p> <p>8 MR. LOCKE: Same objection and as to</p> <p>9 form.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Okay. Now, I also went through</p> <p>12 Exhibit 97, and since we've got numbers here that</p> <p>13 go back to 2002, I looked at how much each of</p> <p>14 these nine panel members have made from serving on</p> <p>15 the panels since 2002.</p> <p>16 We'll start with Ronald Shank. You can</p> <p>17 see that I've totaled up 2002 here, 2003, all the</p> <p>18 way down to 2011. And it shows from 2002 to 2011,</p> <p>19 PCPC paid Ronald Shank over \$216,000.</p> <p>20 MR. LOCKE: Objection. Beyond the</p> <p>21 scope. Mr. Pollack was designated for this topic.</p> <p>22 In addition, Exhibit 96, if that's what</p> <p>23 you're referring to, is the expenses, not --</p> <p>24 MR. MEADOWS: I'm referring to</p> <p>25 Exhibit 97.</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Donald Belsito, from 2002 to 2011 was</p> <p>3 paid in excess of \$214,000. Do you see what I'm</p> <p>4 talking about?</p> <p>5 MR. LOCKE: Same objection, beyond the</p> <p>6 scope?</p> <p>7 THE WITNESS: I see what you're showing</p> <p>8 me.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Okay. Ronald Hill, he appears to have</p> <p>11 only worked on panels from 2009 to 2011. He was</p> <p>12 paid in excess of \$70,000 in that time period.</p> <p>13 A Yeah.</p> <p>14 MR. LOCKE: Same objection. Beyond the</p> <p>15 scope.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q Curtis Klaassen, from 2002 to 2011, he</p> <p>18 was paid in excess of \$158,000.</p> <p>19 A And just to make the point --</p> <p>20 MR. LOCKE: Same objection. Beyond the</p> <p>21 scope.</p> <p>22 THE WITNESS: I mean, this is not just</p> <p>23 attending the panel meetings. This is preparation</p> <p>24 for them.</p> <p>25 BY MR. MEADOWS:</p>
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<p>1 MR. LOCKE: Okay. Withdraw that</p> <p>2 portion.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q I similarly did the same for Thomas</p> <p>5 Slaga, as you can see here, showing that for 2002</p> <p>6 to 2011, he was paid over \$188,000 from PCPC.</p> <p>7 MR. LOCKE: Same --</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q Do you see that?</p> <p>10 MR. LOCKE: Same objection. Beyond the</p> <p>11 scope. Mr. Pollack was designated for this topic.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Similarly, I did the same with Paul</p> <p>14 Snyder. From 2002 to 2011, he was paid in excess</p> <p>15 of \$242,000 from PCPC. Do you see that?</p> <p>16 MR. LOCKE: Same objection. Mr. Pollack</p> <p>17 was designated for this topic.</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Do you see what I'm talking about?</p> <p>20 A I see what you're showing me, yes.</p> <p>21 Q Okay. Same for Wilma Bergfeld, from</p> <p>22 2002 to 2011, and she was paid by PCPC in excess</p> <p>23 of \$231,000.</p> <p>24 MR. LOCKE: Same objection. Beyond the</p> <p>25 scope.</p>	<p>1 Q Sure. Exactly. This is for the work</p> <p>2 that they performed for the PCPC, correct?</p> <p>3 A Correct.</p> <p>4 MR. LOCKE: For the CIR.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q They worked for the CIR, and they were</p> <p>7 paid by the PCPC, correct?</p> <p>8 MR. LOCKE: Objection to form.</p> <p>9 THE WITNESS: The money to CIR comes</p> <p>10 from PCPC.</p> <p>11 BY MR. MEADOWS:</p> <p>12 Q Daniel Liebler, he worked for two</p> <p>13 years -- or, excuse me, from 2009 to 2011, was</p> <p>14 paid in excess of \$82,000.</p> <p>15 MR. LOCKE: Objection. Beyond the</p> <p>16 scope.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q James Marks, he was on the panel from</p> <p>19 2002 to 2011 and was paid in excess of \$170,000.</p> <p>20 Do you see that?</p> <p>21 MR. LOCKE: Objection. Beyond the</p> <p>22 scope.</p> <p>23 THE WITNESS: For the 10 years, it looks</p> <p>24 like.</p> <p>25 BY MR. MEADOWS:</p>

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<p>1 Q And so I added all that up, and those</p> <p>2 panel members, having worked from 2002 to 2011,</p> <p>3 were paid by PCPC \$1.575 million.</p> <p>4 MR. LOCKE: Objection to form and beyond</p> <p>5 the scope.</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q Would that surprise you at all?</p> <p>8 MR. LOCKE: Objection to form, beyond</p> <p>9 the scope.</p> <p>10 THE WITNESS: They are very highly</p> <p>11 qualified MDs, Ph.D.s, consulting fees. That's</p> <p>12 what they are. That's -- we're talking 10 years.</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q By the time they get to the talc review</p> <p>15 in 2012, these panel members have been paid almost</p> <p>16 \$1.6 million over the course of a decade.</p> <p>17 Correct?</p> <p>18 A These are -- these are people --</p> <p>19 MR. LOCKE: Objection to form and beyond</p> <p>20 the scope.</p> <p>21 THE WITNESS: These are highly paid</p> <p>22 people in their regular jobs. I mean, that's --</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q And then they are asked to review an</p> <p>25 ingredient that's a principal ingredient in many</p>	<p>1 know what it's worth.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Well, we saw documents from PCPC earlier</p> <p>4 that said that, didn't they?</p> <p>5 MR. LOCKE: Objection to form and beyond</p> <p>6 the scope.</p> <p>7 THE WITNESS: The cosmetic industry is</p> <p>8 worth a lot of money, yes, of course.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Yeah, right. And these reviewers,</p> <p>11 having made \$1.6 million before being asked to</p> <p>12 review talc, they're being asked to essentially</p> <p>13 tell the people who have been paying them that</p> <p>14 their ingredient is safe or unsafe, right?</p> <p>15 MR. LOCKE: Objection to form.</p> <p>16 MS. FRAZIER: Objection to form.</p> <p>17 MR. LOCKE: And beyond the scope.</p> <p>18 THE WITNESS: Again, I would just say</p> <p>19 these are people who's reputate- -- who have</p> <p>20 reputations in their areas, and the idea that</p> <p>21 for -- you know, you're -- you're summing all the</p> <p>22 money together over 10 years, and the idea that</p> <p>23 for a single ingredient that they would compromise</p> <p>24 their reputation I think is -- that doesn't make</p> <p>25 sense.</p>
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<p>1 cosmetics, isn't it?</p> <p>2 A I don't know that I would -- I mean,</p> <p>3 they're asked to review cosmetic -- everything</p> <p>4 they're reviewing is a cosmetic ingredient.</p> <p>5 Q Correct. But talc is --</p> <p>6 A So they're important.</p> <p>7 Q Talc is found in lots of cosmetics,</p> <p>8 isn't it?</p> <p>9 A There are other ingredients they</p> <p>10 reviewed that are found in lots too, but, yes,</p> <p>11 talc is found in a lot.</p> <p>12 Q And we saw some numbers earlier that</p> <p>13 said that the cosmetic industry is a -- is worth</p> <p>14 hundreds of billions of dollars, isn't it?</p> <p>15 MR. LOCKE: Objection to form and beyond</p> <p>16 the scope.</p> <p>17 THE WITNESS: I mean, these are people</p> <p>18 when they're asked to review, I mean, they have</p> <p>19 their reputations.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q The cosmetic industry is worth hundreds</p> <p>22 of billions of dollars, isn't it?</p> <p>23 MR. LOCKE: Objection to form and beyond</p> <p>24 the scope.</p> <p>25 THE WITNESS: I don't -- I really don't</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Well, you don't think money has</p> <p>3 influence?</p> <p>4 MR. LOCKE: Objection to form and beyond</p> <p>5 the scope.</p> <p>6 MR. GOLOMB: Let me just say something</p> <p>7 for the record. Just put this objection to rest.</p> <p>8 Mr. Pollack, first of all, was not asked</p> <p>9 any of these questions.</p> <p>10 MR. LOCKE: He was designated.</p> <p>11 MR. GOLOMB: Excuse me?</p> <p>12 MR. LOCKE: He was designated for these</p> <p>13 financial issues.</p> <p>14 MR. GOLOMB: I won't interrupt you.</p> <p>15 Don't interrupt me, okay? Do we have an agreement</p> <p>16 on that?</p> <p>17 MR. LOCKE: No.</p> <p>18 MR. GOLOMB: Okay. Mr. Pollack was</p> <p>19 designated under topic 3, 10(d), which is "PCPC's</p> <p>20 relationship with CIR, including funding,</p> <p>21 staffing, membership, formal and informal</p> <p>22 meetings, committee and/or subcommittees," and he</p> <p>23 was not asked any of these questions that</p> <p>24 Mr. Meadows is now asking.</p> <p>25 Dr. Loretz, on the other hand, under</p>

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<p>1 10(a) was designated for the CIR safety assessment</p> <p>2 of talc, which is clearly the CIR report,</p> <p>3 including the timeline, process, funding,</p> <p>4 individuals and entities involved in the process,</p> <p>5 meetings, drafting of the scientific literature</p> <p>6 review, draft report and final safety assessment.</p> <p>7 It's not beyond the scope.</p> <p>8 MR. LOCKE: We disagree.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Now, Dr. Loretz, that's just the amount</p> <p>11 of money that was paid before they were asked to</p> <p>12 review talc. In the course of the year of 2012,</p> <p>13 while they were reviewing talc, they were paid an</p> <p>14 additional \$248,000, bringing the total to</p> <p>15 \$1.82 million that this panel had been paid by the</p> <p>16 time they made a report on talc.</p> <p>17 Does that surprise you at all?</p> <p>18 MR. LOCKE: Objection to form and beyond</p> <p>19 the scope.</p> <p>20 THE WITNESS: I would just say that</p> <p>21 these -- the reason that they're -- I mean, we --</p> <p>22 they're highly qualified people, and as</p> <p>23 consultants, they're going to make -- I mean, we</p> <p>24 pay them reasonably. And their -- you know, they</p> <p>25 make this much money in their regular jobs. I</p>	<p>1 witness.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q Snyder, that's five of them. Slaga,</p> <p>4 that's six of them. Shank, that's seven of them.</p> <p>5 And seven of the nine members had been</p> <p>6 on that panel for over 10 years by the time they</p> <p>7 ruled on talc. Over -- year after year after</p> <p>8 year, they're getting paid by PCPC and industry to</p> <p>9 review their ingredients and tell them that</p> <p>10 they're safe. Isn't that what's going on?</p> <p>11 MR. LOCKE: Objection --</p> <p>12 MS. FRAZIER: Object to form.</p> <p>13 MR. LOCKE: -- to form.</p> <p>14 THE WITNESS: These are highly, highly</p> <p>15 qualified, highly paid outside of this -- working</p> <p>16 for CIR, professionals. I mean...</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q I'm going to switch gears a little bit.</p> <p>19 I have a few questions about a few documents.</p> <p>20 (Exhibit No. 98 was marked for</p> <p>21 identification.)</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q Exhibit 98. This is Bates No. PCPC</p> <p>24 67797, correct?</p> <p>25 A Yes.</p>
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<p>1 mean...</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q You know, I'm not against people making</p> <p>4 money. But what we did see as we went through</p> <p>5 these is this is not like a panel that's put</p> <p>6 together on a one-, two-time basis. These folks</p> <p>7 are repeat customers, aren't they?</p> <p>8 MR. LOCKE: Objection to form.</p> <p>9 THE WITNESS: It's a standing panel.</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q James Marks, he did this for 10 years,</p> <p>12 didn't he?</p> <p>13 A That --</p> <p>14 Q By the time he did talc, right?</p> <p>15 A That is likely correct, yes.</p> <p>16 Q Klaassen, he did it for 10 years by the</p> <p>17 time he did talc, right?</p> <p>18 A Yes.</p> <p>19 Q Belsito, he did it for 10 years by the</p> <p>20 time he did talc, right? That's three of them.</p> <p>21 A They're long-term members of the expert</p> <p>22 panel --</p> <p>23 Q Bergfeld, that's four of them.</p> <p>24 A -- that's correct.</p> <p>25 MR. LOCKE: Please don't interrupt the</p>	<p>1 Q Okay. What is this?</p> <p>2 A I don't know.</p> <p>3 Q It's entitled "Talc Refs." You haven't</p> <p>4 seen this one?</p> <p>5 A No.</p> <p>6 Q Angela Howard, Toxicologist, do you know</p> <p>7 who she is?</p> <p>8 A She used to work for CIR.</p> <p>9 Q It looks like this is dated March of</p> <p>10 2009, correct?</p> <p>11 A Yes.</p> <p>12 Q "Subject: Reference Request."</p> <p>13 A Yes. And Whit Price is someone that --</p> <p>14 he provides references obviously.</p> <p>15 Q It appears to be a three-page document.</p> <p>16 If you flip over to the last page, it</p> <p>17 appears to be a document entitled "Communications</p> <p>18 to the Editor," right?</p> <p>19 MR. LOCKE: I'm going to object. These</p> <p>20 seem to be unrelated pages. Perhaps they're</p> <p>21 related. If they are, I can't tell what they are.</p> <p>22 They are consecutively numbered, but I don't know</p> <p>23 if they go together.</p> <p>24 MR. MEADOWS: Well, Mr. Locke, that's</p> <p>25 the way they were produced to us, representing</p>

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<p>1 that these three documents are -- or these three 2 pages are one document. 3 MR. LOCKE: I'm not sure that's correct. 4 They could have been a 96 and a -- and a 800 page 5 after this, and I don't know that they were all 6 together. 7 BY MR. MEADOWS: 8 Q Well, let's look at this then. The 9 first page. It has a reference to number 20, 10 Dresler, CM. Do you see that? 11 A Yes. 12 Q "Systemic Distribution of Talc." 13 No abstract available. It has a PubMed 14 reference there. 15 Do you see that? 16 A Yes. 17 Q Okay. All right. If you flip over to 18 the last page there, there we find the referenced 19 article, correct? "Systemic Distribution of 20 Talc," and Dresler, right? 21 A Yeah. I'm -- well -- 22 MR. LOCKE: Objection. Calling it an 23 article. It's a letter to the editor. 24 THE WITNESS: Yes, that's what I was 25 going to say. It's -- it's a letter. That's why</p>	<p>1 trial, I have been very sensitive to the potential 2 safety issues relative to insufflation. For this 3 reason, I believe we need further studies 4 exploring the results of disseminated talc. 5 "Somewhat surprisingly, all talcs are 6 not equal. Crystal structure and size of the talc 7 particle may vary depending on the location of the 8 talc mine. Perhaps it is this variability and the 9 size or structure of the talc that determines the 10 permeability or distribution, and thus, potential 11 toxicity of interpleural talc. 12 "Approximately 20 -- 250,000 people each 13 year in the United States have a malignant pleural 14 effusion. Talc is the most effective sclerosing 15 agent identified to date. Thus, it's important to 16 confirm its safety. I was very pleased to read 17 this safety by Werebe and colleagues to hope that 18 further discussion and research is engendered." 19 Did I read that correctly? 20 A Yes. 21 Q Okay. Obviously this Dr. Dresler is an 22 expert on pleurodesis, no? 23 MR. LOCKE: Objection to form. 24 THE WITNESS: I really don't know what 25 her background is.</p>
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<p>1 I'm trying to figure out if that is really the 2 same thing, but -- looks like it is. 3 BY MR. MEADOWS: 4 Q Looks like it is? 5 A Yes. 6 Q All right. Let's read this letter to 7 the editor. 8 "The recent article by Werebe and 9 colleagues, January 1999, concerning systemic 10 distribution of talc was a fascinating and timely 11 study. This group has a very large experience 12 with talc pleurodesis" -- 13 You -- you've referred to that over the 14 last two days, haven't you. Pleurodesis? 15 A Yes. 16 Q -- "and they are to be commended in 17 pursuing not only efficacy of the procedure but 18 also the safety, as they are aware a large 19 multicentric trial is underway in the United 20 States exploring the efficacy of talc pleurodesis 21 administered either through a chest tube as a 22 slurry or via video-assisted fluoroscopy as an 23 insufflated mist in patients with a malignant 24 plural effusion. 25 "As co-principal investigator of this</p>	<p>1 BY MR. MEADOWS: 2 Q Well, she claims to be a co-principal 3 investigator. Did you see that? 4 A Yes. 5 Q Okay. And she talks about how talc can 6 be toxic, correct? 7 A I think she says: "I have been very 8 sensitive to potential safety issues, and I 9 believe we need further studies. Important to 10 confirm its safety." 11 Q Okay. In any event, this is an article 12 that somebody at PCPC was told to look at, no? 13 A That's what it looks to be, yes. 14 Q In particular, Angela Howard? 15 A Yes. 16 Q Toxicologist? 17 A Yes. 18 Q There's a handwritten note up here that 19 says "Not Used." 20 A Which also says: "Letter goes with the 21 publication," what looks to be a real article of 22 several pages long. This is really her just 23 saying this is an important and good study. So my 24 assumption would be that's why they would not use 25 this letter.</p>

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<p>1 Q You're saying that the letter goes 2 with -- what are you interpreting that as? 3 A This -- I'm assuming "Not Used" refers 4 to this letter, which is simply a letter saying 5 this other study is -- is a good study. Or is an 6 important study. 7 Q Which other study are you talking about? 8 A It's the recent article by W-E-R-E-B-E. 9 Q Okay. So you don't interpret this to 10 mean that the CIR is not going to use a letter to 11 the editor or consider a letter to the editor 12 in -- in their review of talc? 13 MR. LOCKE: Objection to form. 14 THE WITNESS: No, I -- I don't know what 15 it means. I -- it just says "Letter goes with 16 this." So -- I mean, I can speculate about what 17 it might mean, but I don't know what it means. 18 BY MR. MEADOWS: 19 Q Do you think we'd find a reference to 20 this letter to the editor in the talc review? 21 A Based on it saying "Not Used," I would 22 think probably not. 23 Q Okay. 24 (Exhibit No. 99 was marked for 25 identification.)</p>	<p>1 Q Do you know where she is now? 2 A I think I knew that she went to EPA, but 3 whether she's still there now, I really have no 4 idea. 5 Q So this one appears to reference an 6 attached article. So we're looking at Bates 7 PCPC_MDL_22149. And flipping over two pages is 8 where I find the page that gives me the title of 9 the article referenced. 10 Do you see where I'm talking about? 11 A Yes. 12 Q This article is called "Toxic Effects of 13 Surgical Glove Powders on the Eye." Did I read 14 that correctly? 15 A Yes. 16 Q And flipping back over to the first 17 page, it has the note "Not Used" again, correct? 18 A Yes. 19 Q Have you ever read this article? 20 A No. 21 Q Okay. All right. 22 (Exhibit No. 100 was marked for 23 identification.) 24 BY MR. MEADOWS: 25 Q All right. I'm going to show you what I</p>
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<p>1 BY MR. MEADOWS: 2 Q All right. Let me show you what I 3 marked as Exhibit 99. 4 It's a similar document, isn't it? 5 A It looks to be, yes. 6 Q Angela Howard again? 7 A Yes. 8 Q She still works for -- 9 A No. 10 Q -- CIR? No. 11 Again, this is back in 2009, right? 12 A Yes. 13 Q What was going on with respect to talc 14 back in 2009 such that the CIR would have been 15 looking at this? 16 A I think we've seen before, I think they 17 talked about reviewing it then, and -- and didn't. 18 So apparently these were preliminary, going after 19 references, but that's what I would assume. 20 Q And why was it not reviewed in 2009? 21 A I -- I don't know. I mean, perhaps 22 Angela Howard left. Perhaps that had something to 23 do with it. I don't know. 24 Q What was her position at CIR? 25 A It says her title was toxicologist.</p>	<p>1 marked as Exhibit 100. 2 And just ask if you can identify what 3 this document is. 4 Let me get the -- I tell you what, I 5 better put the Bates number on there or I'll get 6 in trouble. PCPC_MDL_127808. 7 A So this looks to be a memo that goes out 8 from the director of CIR to panel members and 9 liaisons with agenda for the meeting coming up and 10 various other pieces of information relevant to 11 the upcoming meeting. 12 Q And this would have been the meeting -- 13 this was late 2012, correct? 14 A That's what it says, yes. 15 Q Okay. It says: "Enclosed are the 16 agenda and accompanying materials for the 125th 17 CIR Expert Panel Meeting to be held December 10 18 and 11 in Washington, D.C." Correct? 19 A Yes. 20 Q So, is that the way it works, that the 21 panel members get the agenda and the accompanying 22 materials about a month before the meeting? 23 A That's about right, yes. 24 Q It looks like this was actually a little 25 bit less than a month.</p>

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<p>1 A Yes.</p> <p>2 Q "The meeting agenda includes</p> <p>3 consideration of 13 ingredient groups, advancing</p> <p>4 the process, two rereviews, consideration of new</p> <p>5 data on phthalates and PEG cocamine, and review of</p> <p>6 available data on infant skin, including dermal</p> <p>7 penetration."</p> <p>8 Did I read that correctly?</p> <p>9 A Oh, I'm sorry.</p> <p>10 Q I'm looking at the first paragraph.</p> <p>11 A Right. That looks -- yes, I believe you</p> <p>12 did read it correctly.</p> <p>13 Q So they're actually -- for that</p> <p>14 particular meeting, they were looking at 13</p> <p>15 ingredients, right?</p> <p>16 A Ingredient groups, right, and reports.</p> <p>17 Q Ingredient groups, so it may have been a</p> <p>18 whole lot more ingredients, but it was 13</p> <p>19 different groups, right?</p> <p>20 A Yes.</p> <p>21 Q But talc was an ingredient group on a --</p> <p>22 of its own?</p> <p>23 A It was -- right, that was the only</p> <p>24 report -- that was the only ingredient in that</p> <p>25 report, correct. So it would have been one of the</p>	<p>1 asbestiform fibers. This safety assessment has</p> <p>2 generated a good deal of interest, and a number of</p> <p>3 comments and data have been received. Where the</p> <p>4 data were from scientific studies, we've captured</p> <p>5 that information, published and unpublished.</p> <p>6 Where the data were press reports, we did not</p> <p>7 capture that information. If we have all the data</p> <p>8 we need, we can issue a tentative report. If not,</p> <p>9 we should ask for whatever additional data are</p> <p>10 needed in a formal insufficient data</p> <p>11 announcement."</p> <p>12 Do you know if anybody issued a formal</p> <p>13 insufficient data announcement?</p> <p>14 A I don't recall.</p> <p>15 Q And why would they make the comment,</p> <p>16 "Where the data were press reports, we did not</p> <p>17 capture that information"?</p> <p>18 A I think -- and talc is relatively</p> <p>19 unique, but I'm not -- I don't know it's the only</p> <p>20 one, where there are more press reports, and I</p> <p>21 think this is just saying that we didn't count</p> <p>22 that as data. We have scientific studies on that,</p> <p>23 published and unpublished, but we're not including</p> <p>24 press reports, which I -- I mean, I can't think of</p> <p>25 a time when they ever would have included a press</p>
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<p>1 13.</p> <p>2 And just to point out too, I mean, along</p> <p>3 with this, they get -- obviously they get the</p> <p>4 reports as well, so that's part of their review.</p> <p>5 Q Okay. Slip over to the next page.</p> <p>6 Under "Draft Reports," there are five</p> <p>7 draft reports under green cover. What does "green</p> <p>8 cover" mean?</p> <p>9 A They use different colors to designate</p> <p>10 whether it's a draft report, a tentative report, a</p> <p>11 scientific literature review or a final report.</p> <p>12 Q Okay. And then if you go down, it says,</p> <p>13 number 5, "Talc," right?</p> <p>14 A Yes.</p> <p>15 Q "The SLR" -- and what does that stand</p> <p>16 for again?</p> <p>17 A Scientific literature review.</p> <p>18 Q -- "for talc was issued on August 21,</p> <p>19 2012. One old issue regarding talc and asbestos</p> <p>20 we think is a nonissue because the specifications</p> <p>21 for cosmetic talc state that it must be</p> <p>22 asbestos-free."</p> <p>23 Did I read that right?</p> <p>24 A Yes.</p> <p>25 Q "And that it does not contain</p>	<p>1 report in a CIR report.</p> <p>2 Q Okay.</p> <p>3 (Counsel conferring.)</p> <p>4 (Exhibit No. 101 was marked for</p> <p>5 identification.)</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q All right. I show you what I marked as</p> <p>8 Exhibit 101. Bates No. PCPC_MDL_145272.</p> <p>9 And you'll notice that this is from a</p> <p>10 time period -- well, it's entitled "CIR Expert</p> <p>11 Panel Expense Report." It's for Dr. Belsito. And</p> <p>12 you'll notice that there are some dates from 2017</p> <p>13 on here.</p> <p>14 I'm just curious as to what this is and</p> <p>15 why we haven't seen more of these in the documents</p> <p>16 that were produced to us. Because I -- we didn't</p> <p>17 see any others from any of the time periods.</p> <p>18 MR. LOCKE: Objection to form and beyond</p> <p>19 the scope. This was a topic for Mr. Pollack.</p> <p>20 You can answer if you know.</p> <p>21 THE WITNESS: I mean, I've never seen</p> <p>22 documents like this. I don't get involved in that</p> <p>23 at all. I mean, it appears to be an expense</p> <p>24 report, but I just couldn't answer your question.</p> <p>25 I just don't know.</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. Good enough. Thank you.</p> <p>3 All right. So we're back to talking a</p> <p>4 little bit more about transparency. Okay. And</p> <p>5 your position that the CIR is a transparent</p> <p>6 process, right?</p> <p>7 A Yes.</p> <p>8 (Exhibit No. 102 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Okay. So the next document I'd like to</p> <p>12 look at is Exhibit 102. And this is</p> <p>13 PCPC_MDL_23425. Correct?</p> <p>14 A Yes.</p> <p>15 Q And it is from the letterhead -- or on</p> <p>16 the letterhead of Center for Regulatory</p> <p>17 Effectiveness, right?</p> <p>18 A Yes.</p> <p>19 Q We talked about the CR -- CRE, you and I</p> <p>20 did, several weeks ago in your deposition,</p> <p>21 correct?</p> <p>22 A Correct.</p> <p>23 Q Okay. And I believe we established then</p> <p>24 that PCPC was aware that Imerys had hired the CRE</p> <p>25 to help them with respect to the CIR process.</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. Other than in the context of</p> <p>3 talc, have you ever seen CRE operating in the</p> <p>4 PCPC/CIR arena?</p> <p>5 A No.</p> <p>6 Q No. It's the only time you've ever seen</p> <p>7 CRE operating in the cosmetic arena as it pertains</p> <p>8 to PCPC and CIR was when they were working with</p> <p>9 Imerys on talc.</p> <p>10 A In relation to CIR, as far as I know,</p> <p>11 that's correct, yes. I mean, as far as I can</p> <p>12 remember, I don't recall anything, correct.</p> <p>13 Q All right. Were you familiar with CRE</p> <p>14 working in any other circles?</p> <p>15 A Related to --</p> <p>16 Q Cosmetics.</p> <p>17 A -- PCPC?</p> <p>18 I think, and this goes to, I guess, our</p> <p>19 interrogatories, I'm not sure if they ever did any</p> <p>20 work beyond -- not in the science area, I don't</p> <p>21 think. I think -- I don't know. There's some</p> <p>22 question they did some work with the international</p> <p>23 department, but I may be wrong about that. But</p> <p>24 I -- so I guess my answer is I don't know.</p> <p>25 But in the science area, I'm not aware</p>
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<p>1 A I --</p> <p>2 MR. LOCKE: Objection to form.</p> <p>3 THE WITNESS: Yeah, I'm not sure. I</p> <p>4 mean, at some point I was aware that I think CRE</p> <p>5 was submitting information.</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q Yeah. And you were aware that they were</p> <p>8 working with Imerys, correct?</p> <p>9 MR. DONATH: Objection to form.</p> <p>10 THE WITNESS: I'm not sure.</p> <p>11 BY MR. MEADOWS:</p> <p>12 Q You're not sure. Okay. If the record</p> <p>13 does show that you were aware of that, would you</p> <p>14 be mistaken right now?</p> <p>15 A Um, yeah, I'm saying I'm not sure. I'm</p> <p>16 not saying no. I just -- I'm not sure what I knew</p> <p>17 about CRE.</p> <p>18 Q So as a refresher, CRE is a group that</p> <p>19 works with industry to -- essentially to make sure</p> <p>20 that they don't get regulated, right?</p> <p>21 MS. FRAZIER: Objection to form.</p> <p>22 MR. LOCKE: Objection to form.</p> <p>23 THE WITNESS: I don't know what they say</p> <p>24 they work on really. They're consultants to</p> <p>25 various industry groups, I think.</p>	<p>1 of anything. I -- certainly we didn't hire them</p> <p>2 for talc.</p> <p>3 Q So you're saying that CRE may have done</p> <p>4 some work for PCPC at some point?</p> <p>5 A I'm saying I don't know. That would be</p> <p>6 in the interrogatories or that was a question for</p> <p>7 Mark. I -- I don't know. I just don't want to</p> <p>8 give you a "no" answer and be wrong.</p> <p>9 Q Okay. In any event, you're the not</p> <p>10 person who would be able to answer that question?</p> <p>11 A Correct. Right.</p> <p>12 Q Okay. So the CRE, they're located in</p> <p>13 Washington, D.C., right?</p> <p>14 A Yes.</p> <p>15 Q According to their letterhead.</p> <p>16 And this letter is dated January 27th of</p> <p>17 2012, right?</p> <p>18 A Yes.</p> <p>19 Q And it's to Monice Fiume, right?</p> <p>20 A Yes.</p> <p>21 Q She's the lead author on the CR -- CIR</p> <p>22 talc report, correct?</p> <p>23 A I -- she and Ivan. I think her name is</p> <p>24 first, so I guess -- I'm going to go with yes.</p> <p>25 Q Yeah. Okay. And this letter is from</p>

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<p>1 William Kelly, right?</p> <p>2 A Yes.</p> <p>3 Q I believe there was some discussion of</p> <p>4 him yesterday. Do I remember that correctly? No?</p> <p>5 A It seems like -- probably, yes.</p> <p>6 Q Okay. All right. There are some</p> <p>7 e-mails where you were on the same e-mail chain as</p> <p>8 him, correct?</p> <p>9 A Yes. At the time IARC, I believe.</p> <p>10 Q Do I remember correctly you actually had</p> <p>11 communications with William Kelly via e-mail at</p> <p>12 some point in time?</p> <p>13 A Not me -- not one on one, no. No. On</p> <p>14 the same e-mail chain related to IARC.</p> <p>15 Q "Subject: Upcoming CIR review of talc</p> <p>16 and CRE submission of relevant information."</p> <p>17 Correct?</p> <p>18 A That's what it says.</p> <p>19 Q "Dear Ms. Fiume: Enclosed with this</p> <p>20 note there should be three items: A large</p> <p>21 compendium of published literature on talc,</p> <p>22 excluding occupational exposures; a bibliography</p> <p>23 showing the citations for all of the items in the</p> <p>24 literature compilation; and number 3, a</p> <p>25 considerable -- considerably long version of the</p>	<p>1 the CRE, the Center for Regulatory Effectiveness,</p> <p>2 was misrepresenting their role in the CIR process?</p> <p>3 MR. DONATH: Objection.</p> <p>4 MR. LOCKE: Objection to form.</p> <p>5 THE WITNESS: If we didn't see this, I</p> <p>6 don't -- we wouldn't know that they were</p> <p>7 misrepresenting.</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q So your answer is that you're not aware</p> <p>10 of anybody ever telling Monice Fiume or anybody at</p> <p>11 the CIR that the CRE was actually acting on behalf</p> <p>12 of Imerys?</p> <p>13 MR. DONATH: Same objection.</p> <p>14 MR. LOCKE: Objection to form.</p> <p>15 THE WITNESS: No, I'm not aware that</p> <p>16 that was communicated, if indeed that's correct,</p> <p>17 which --</p> <p>18 BY MR. MEADOWS:</p> <p>19 Q Okay. Now, you would agree that if your</p> <p>20 mantra is transparency, it would be important for</p> <p>21 Mr. Kelly and Imerys to be transparent with the</p> <p>22 CIR, correct?</p> <p>23 MR. DONATH: Objection to form.</p> <p>24 THE WITNESS: I think if someone submits</p> <p>25 information to CIR, they need to be -- yes, they</p>
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<p>1 bibliography with comments and notes added by me.</p> <p>2 Please note that this should not be considered an</p> <p>3 industry submission. CRE is an independent</p> <p>4 organization that has not represented individual</p> <p>5 entities."</p> <p>6 Did I read that correctly?</p> <p>7 A That's what it says.</p> <p>8 Q But that's a misrepresentation, isn't</p> <p>9 it?</p> <p>10 MR. LOCKE: Objection to form.</p> <p>11 THE WITNESS: I mean, I don't -- have</p> <p>12 background information, but if they were being</p> <p>13 paid by Imerys, yes, that is a misrepresentation.</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Okay. Did anybody inform CIR that, Hey,</p> <p>16 this is a miss -- misrepresentation, the</p> <p>17 information you're receiving from the CRE is</p> <p>18 actually being sent on behalf of Imerys?</p> <p>19 A I have never seen this.</p> <p>20 MR. LOCKE: Objection to form.</p> <p>21 THE WITNESS: I've never seen this. I</p> <p>22 don't know that anybody at PCPC ever saw this.</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q Okay. But my question is, did anybody</p> <p>25 ever inform Monice Fiume or anybody at CIR that</p>	<p>1 should not misrepresent themselves, CRE or anyone</p> <p>2 else.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q Because if we're going to be</p> <p>5 transparent, it needs to be across the board,</p> <p>6 right?</p> <p>7 A I mean, if someone just flat out</p> <p>8 misrepresents themselves, of course that's not</p> <p>9 right.</p> <p>10 Q Yeah.</p> <p>11 (Exhibit No. 103 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. MEADOWS:</p> <p>14 Q All right. I show you what I've marked</p> <p>15 as Exhibit 103.</p> <p>16 And this is -- it begins Bates stamp</p> <p>17 number Plaintiff PCPC 132, correct?</p> <p>18 A Yes.</p> <p>19 Q Okay. And it's an e-mail chain,</p> <p>20 correct?</p> <p>21 A It looks to be.</p> <p>22 Q Probably be good for us to just start at</p> <p>23 the beginning of that chain, okay? So we'll flip</p> <p>24 on back.</p> <p>25 So the first e-mail is sent from Monice</p>

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<p>1 Fiume, right?</p> <p>2 A Yes.</p> <p>3 Q And this is in 20 -- June of 2012,</p> <p>4 right?</p> <p>5 A Yes.</p> <p>6 Q Halfway through the year when talc was</p> <p>7 being considered, right?</p> <p>8 A Yes.</p> <p>9 Q And it's to Ivan Boyer. Ivan Boyer is</p> <p>10 one of the reviewers, right?</p> <p>11 A He -- no. Ivan Boyer is a CIR Ph.D.</p> <p>12 toxicologist.</p> <p>13 Q Oh, I'm sorry, yes, correct. But he is</p> <p>14 listed as one of the --</p> <p>15 A One of the authors.</p> <p>16 Q -- authors on the final talc review,</p> <p>17 correct?</p> <p>18 A Yes.</p> <p>19 Q Okay. And I'm sorry, once again, his</p> <p>20 title at CRE -- excuse me, CIR is what?</p> <p>21 A I -- well, first of all, he's not there</p> <p>22 anymore. So --</p> <p>23 Q Was.</p> <p>24 A -- he was a toxicologist. I don't know</p> <p>25 what his exact title was, but he was a Ph.D. --</p>	<p>1 A Well, I don't know what the arrangement</p> <p>2 was. I just know that he did do some consulting</p> <p>3 work, so yes.</p> <p>4 Q And do you know what that consulting</p> <p>5 work was for in particular?</p> <p>6 A The only thing I ever heard specifically</p> <p>7 was I think he had a -- played a role in writing</p> <p>8 up things for publication. That's what I'm</p> <p>9 recalling, that I heard that. But whether that</p> <p>10 was an important piece of his consulting or not, I</p> <p>11 just don't know.</p> <p>12 Q Obviously he's involved in an e-mail</p> <p>13 regarding talc, correct?</p> <p>14 A Yes.</p> <p>15 Q And so he, presumably as part of his</p> <p>16 consulting role, was working on talc.</p> <p>17 A It would appear that way, yes.</p> <p>18 Q Who would know the answers to those</p> <p>19 questions about what his consulting arrangement</p> <p>20 was after he left?</p> <p>21 A I guess CIR.</p> <p>22 Q Any particular person that you know of?</p> <p>23 A Well, I would want to say Lillian Gill,</p> <p>24 except that she's not there anymore. But...</p> <p>25 Q Okay. And when -- when did Lillian Gill</p>
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<p>1 was and is a Ph.D. toxicologist.</p> <p>2 Q Okay. And he's not an epidemiologist,</p> <p>3 is he?</p> <p>4 A No.</p> <p>5 Q Okay. And it's copied to Lillian Gill.</p> <p>6 Who is Lillian?</p> <p>7 A She is the -- was at that time the head</p> <p>8 of CIR. She was the director of CIR. She took</p> <p>9 the place of Alan Andersen, who is also copied.</p> <p>10 Q Okay. Yeah, I was kind of curious about</p> <p>11 that. Why is Alan being copied if he's not there</p> <p>12 anymore?</p> <p>13 A Well, I couldn't answer specifically,</p> <p>14 but I know he did some consulting work for CIR</p> <p>15 following when he left.</p> <p>16 Q Okay. So -- when did he leave? When</p> <p>17 did Alan Andersen leave?</p> <p>18 A Well, this tells me that Lillian Gill</p> <p>19 was there in 2012. So he left before then. I</p> <p>20 believe he was there for a few years, so I don't</p> <p>21 know, 2010, '11.</p> <p>22 Q Okay. Good enough.</p> <p>23 And so when Alan Andersen left, he had</p> <p>24 an arrangement to do some consulting work with</p> <p>25 CIR?</p>	<p>1 leave?</p> <p>2 A Not that long ago. I think maybe a year</p> <p>3 ago. She retired.</p> <p>4 Q And who took her place?</p> <p>5 A Bart Heldreth.</p> <p>6 Q I'm sorry, one more time.</p> <p>7 A I'm sorry. Bart Heldreth.</p> <p>8 Q Heldreth?</p> <p>9 A The one we've seen his name before.</p> <p>10 Q Okay. Bart Heldreth. Okay.</p> <p>11 All right. So let's go through Monice's</p> <p>12 e-mail to Ivan Boyer.</p> <p>13 "Ivan, I have finished entering all of</p> <p>14 the ovarian and endometrial risk studies into my</p> <p>15 table. I will let you if I find and add any more.</p> <p>16 For now it is just the info on the subjects, the</p> <p>17 basic info asked, the stats and the relevant risk.</p> <p>18 I would like to reorganize the personal use</p> <p>19 studies to those indicating risk versus not, but I</p> <p>20 will need your help with that.</p> <p>21 "I have included just about all the</p> <p>22 factors and associated risks given in most papers</p> <p>23 so that the panel can have a clear picture.</p> <p>24 However, as I am looking at the review papers, it</p> <p>25 seems all of those factors can be spun in many</p>

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<p>1 different ways to point different -- to paint</p> <p>2 different pictures.</p> <p>3 "What I am hoping is that you can use</p> <p>4 the table and the review papers to create a</p> <p>5 write-up that lays the many different uses out for</p> <p>6 the panel. It seems this includes, does</p> <p>7 inflammation cause risk, whether the population</p> <p>8 was hospital or population based, each of the</p> <p>9 factors examined during questioning, et cetera,</p> <p>10 et cetera. Does that sound like a reasonable game</p> <p>11 plan?</p> <p>12 "Please let me know your thoughts on</p> <p>13 both strategies, a write-up for the panel, and the</p> <p>14 best way to reorganize the table, i.e., what</p> <p>15 factors should be used to create groupings within</p> <p>16 the table. Thanks, Monice."</p> <p>17 What's -- what part of the process is</p> <p>18 this?</p> <p>19 A Let's see. I think the SLR -- I'm</p> <p>20 trying to think of when the SLR came out. This</p> <p>21 looks -- this looks fairly early in the process</p> <p>22 because she's trying to figure out the best to</p> <p>23 organize tables to lay out the data for the panel.</p> <p>24 So this looks pre-SLR, I would guess.</p> <p>25 Q Okay. All right. And I guess later</p>	<p>1 panel to digest.</p> <p>2 "If risks can be grouped by parameter</p> <p>3 studies, I think that -- studied, I think that</p> <p>4 would be most useful. I just don't know which</p> <p>5 parameters are the most useful. Maybe it can be</p> <p>6 done as additional tables. Maybe in Table 8."</p> <p>7 What are these tables that they're</p> <p>8 talking about?</p> <p>9 A I assume they're talking about a good</p> <p>10 deal of CIR reports they arrange data in tables.</p> <p>11 Just kind of a safe space -- space saving -- they</p> <p>12 do a lot of different tables, so...</p> <p>13 Q Okay. Now, there's a series of</p> <p>14 exchanges about tables. And then on July 2nd,</p> <p>15 Ivan Boyer sends one to Monice, and says:</p> <p>16 "Monice, I think I figured out why there is no</p> <p>17 relative risk in some spots of Table 8 for the</p> <p>18 Gates paper, but the differences in percentage</p> <p>19 seem small, and it's not obvious why they would be</p> <p>20 so emphatically statistically -- statistically</p> <p>21 significantly different in the second set of</p> <p>22 p-values. I'm reworking that reference a bit.</p> <p>23 There was definitely a learning curve in writing</p> <p>24 this paper."</p> <p>25 I read that correctly?</p>
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<p>1 that same day, Ivan Boyer responds.</p> <p>2 It says: "Monice, I think you did a</p> <p>3 great job summarizing the voluminous information</p> <p>4 on talc. I'm going to think about your proposed</p> <p>5 strategies for a write-up and table</p> <p>6 reorganization, and get back to you early next</p> <p>7 week. Of note, chronic inflammation is always an</p> <p>8 important risk factor. Hospital versus population</p> <p>9 based studies each have their own limitations, et</p> <p>10 cetera."</p> <p>11 And then he talks about a computer issue</p> <p>12 that he's having.</p> <p>13 And I guess later that same day she</p> <p>14 responds to him, correct?</p> <p>15 A Yes.</p> <p>16 Q In part, after they exchange information</p> <p>17 about laptop crashes, she says: "Thanks for</p> <p>18 looking at the table. I have to say it's probably</p> <p>19 one of the longest tables ever created in our</p> <p>20 reports. In addition to rearranging the studies</p> <p>21 in the table, you may have noticed that right now</p> <p>22 they are by study year. I'd like to create tables</p> <p>23 similar to those in some of the meta-analysis that</p> <p>24 have been done. While Table 8 has the complete</p> <p>25 info, I think it will be very difficult for the</p>	<p>1 A Yes.</p> <p>2 Q Okay. And then there's some more</p> <p>3 exchanges. And then I want to go -- I want to get</p> <p>4 to what would be the second to last -- excuse me,</p> <p>5 I guess the third to last e-mail. And that's the</p> <p>6 one on July 2nd at 5:11 p.m.</p> <p>7 Are you with me?</p> <p>8 A Yeah, I think that's the fourth to last,</p> <p>9 but, yeah.</p> <p>10 Q Okay. Again, now neither of these folks</p> <p>11 are epidemiologists, are they?</p> <p>12 A No.</p> <p>13 Q Okay. And we've already established</p> <p>14 there were not any epidemiologists on the panel,</p> <p>15 correct?</p> <p>16 A That's correct.</p> <p>17 Q Okay. So Ivan Boyer on July 2nd, 2012,</p> <p>18 to Monice Fiume.</p> <p>19 "Thanks, Monice. I'm going over the</p> <p>20 reviews/meta-analyses now to refresh my memory. I</p> <p>21 did not have any real problems with Table 8, but I</p> <p>22 am guided by several principles, which enabled</p> <p>23 fairly quick digestion of the material, and</p> <p>24 probably need to be emphasized to the panel in</p> <p>25 some way to speed up the review of the table."</p>

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<p>1 THE REPORTER: Could you slow down just</p> <p>2 a little?</p> <p>3 MR. MEADOWS: I'm sorry.</p> <p>4 THE REPORTER: "I am guided by several</p> <p>5 principles."</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q Okay. "... which enabled fairly quick</p> <p>8 digestion of the material, and probably need to be</p> <p>9 emphasized to the panel in some way to speed up</p> <p>10 the review of the table. For example," the first</p> <p>11 bullet point, A relative risk estimate of</p> <p>12 approximately 2 is small.</p> <p>13 Did I read that correctly?</p> <p>14 A Yes.</p> <p>15 Q And you agree with that?</p> <p>16 A I think that's a fairly common</p> <p>17 understanding in epidemiology.</p> <p>18 Q Do you think epidemiologists use that</p> <p>19 type of language when they're talking about</p> <p>20 relative risk?</p> <p>21 MR. LOCKE: Objection to form and scope.</p> <p>22 THE WITNESS: I'm not an epidemiologist,</p> <p>23 so I don't --</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q And neither are these two folks who are</p>	<p>1 and the inconsistencies among the talc studies, in</p> <p>2 particular, are driving the controversies)."</p> <p>3 Did I read that correctly?</p> <p>4 A Yes.</p> <p>5 Q Do you agree or disagree with what was</p> <p>6 written there?</p> <p>7 MR. LOCKE: Objection to form and beyond</p> <p>8 the scope.</p> <p>9 THE WITNESS: I think --</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q Or do you have an opinion on it?</p> <p>12 A Yeah, I think that's -- that's</p> <p>13 reasonable, yes.</p> <p>14 Q Now, there continues to be this</p> <p>15 reference to proving cause and effect. Right?</p> <p>16 A Yes.</p> <p>17 Q But that's not the standard for</p> <p>18 determining whether an ingredient is safe, is it?</p> <p>19 MR. LOCKE: Objection. Beyond the</p> <p>20 scope.</p> <p>21 THE WITNESS: You're talking about the</p> <p>22 CIR procedures?</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q I'm talking about the definition of</p> <p>25 "safety" under the CIR procedures, yes.</p>
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<p>1 making these tables, are they?</p> <p>2 A That's correct.</p> <p>3 Q "A confidence interval that includes 1.0</p> <p>4 means that the relative risk is not statistically</p> <p>5 significant. There are nonstatistically</p> <p>6 significant results and statistically significant</p> <p>7 results. There are no 'marginally significant' or</p> <p>8 'nonstatistically significant trends,' and to</p> <p>9 highlight results as such (as is done in some</p> <p>10 paper) can be misleading at best."</p> <p>11 Did I read that correctly?</p> <p>12 A I believe you did.</p> <p>13 Q Let's skip down to the third bullet</p> <p>14 point on that page.</p> <p>15 "A statistically significant positive</p> <p>16 association, as signified by a small relative</p> <p>17 risk, between exposure and the incidence of</p> <p>18 ovarian cancer in an epidemiological study only</p> <p>19 suggests an association between these parameters,</p> <p>20 but is far from proving a cause-and-effect</p> <p>21 relationship (particularly given the weaknesses</p> <p>22 in, and the inconsistencies among, the studies</p> <p>23 summarized in Table 8 (in general, the weaknesses</p> <p>24 of these types of studies are common weaknesses of</p> <p>25 epidemiological studies; the small relative risk</p>	<p>1 MR. LOCKE: Objection. Beyond the</p> <p>2 scope.</p> <p>3 MR. GOLOMB: Was there an answer to that</p> <p>4 question?</p> <p>5 MR. LOCKE: I'm not sure there's a</p> <p>6 question. Do you want to repeat the question?</p> <p>7 MR. MEADOWS: Yeah, my last question.</p> <p>8 (Whereupon, the requested record</p> <p>9 was read.)</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q So the question is cause and effect --</p> <p>12 A I -- I --</p> <p>13 Q -- that's not a -- that's not an issue</p> <p>14 that you find being required under the -- the CIR</p> <p>15 safety standard, is it?</p> <p>16 MR. LOCKE: Objection to form.</p> <p>17 THE WITNESS: I -- I don't read the CIR</p> <p>18 safety standard the way you do.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Do you find the word "cause" anywhere in</p> <p>21 the definition of "safety"?</p> <p>22 MR. LOCKE: Objection. Asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: As we said this morning,</p> <p>25 I -- I think it's implied.</p>

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<p>1 (Exhibit No. 104 was marked for 2 identification.) 3 BY MR. MEADOWS: 4 Q All right. Next document I want to talk 5 about is Exhibit 104. 6 All right. So 104 is Bates-numbered 7 PCPC_MDL_103539, correct? 8 A Yes. 9 Q Okay. And what is this? 10 A So this is after a CIR -- hang on a 11 second. Let me make sure I'm telling you this 12 right. 13 Oh, I'm sorry. This is -- this is 14 another pre-meeting. I would think it's usually 15 part of the -- like the kind of package we looked 16 at before where there's a cover sheet, and then 17 there's the agenda, and then there's notes on 18 that. 19 Q Okay. So it's entitled "125th Cosmetic 20 Ingredient Review Expert Panel Meeting, 21 December 10-11, 2012." Correct? 22 A Yes. 23 Q In Washington, D.C., right? 24 A Yes. 25 Q And doctor -- it's called</p>	<p>1 Q Okay. Bonuses for CIR staff? 2 A Yes. 3 Q And would that include anybody who works 4 for CIR? 5 A That's who CIR staff is. Did you mean 6 expert panel members? 7 Q Yes. 8 A I would certainly not think so, no. 9 Q All right. Flipping on over to the 10 second to last page. 11 It's going to be the third to last page. 12 All right. Are you with me? 13 A Maybe not, since I'm on the fourth to 14 last page. Okay, now I am. 15 Q Okay. So it's Bates 544 at the bottom? 16 A Yes. 17 Q Okay. And starting with the word 18 "Green" there. 19 A Right. 20 Q "Green MF/IB." 21 A Yes. 22 Q And you referenced -- 23 A IB. It stands for Ivan, to it's "I" 24 actually. 25 Q Okay. So you referenced "green"</p>
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<p>1 "Dr. Bergfeld's Annotated Agenda," right? 2 A Yeah. I'm not sure what that means, but 3 Dr. Bergfeld is, of course -- she is the chair of 4 CIR expert panel. 5 Q Okay. All right. Just a couple of 6 things I wanted to ask about that are in here. 7 We'll start with the first page. I'm a 8 little curious, and I just want to ask you about 9 it. Under 8:30 a m., "Welcome to the 125th Expert 10 Panel Meeting" -- 11 A Yes. 12 Q -- it says: "This year Lezlee 13 Westine" -- 14 A Westine. 15 Q Westine. I'll get it eventually. 16 -- "established a President's Award fund 17 to support bonuses for work well done. Lillian 18 and I recognized everyone in the CIR at one level 19 or other, and in time for Christmas shopping. 20 Next year, I'd like you all to be thinking about 21 the work of CIR staff and who you think is worthy 22 of recognition based on what you see!" 23 What is -- just what is that referring 24 to? 25 A Well, I think it's referring to bonuses.</p>	<p>1 earlier, right? We talked about that. 2 A Yes. 3 Q And I guess there's a color coding 4 system for based on where the review is in the 5 process. 6 A Correct. 7 Q Okay. And green means what? 8 A Well, in here it looks like it means 9 scientific literature review. I'm not sure if 10 they're consistent. They may be, but I don't pay 11 that much attention. 12 Q And what does "MF/IB" means? 13 A That stands for Monice Fiume, Ivan 14 Boyer. 15 Q Okay. All right. So let's go through 16 this. 17 "Talc. Dr. Belsito will report in the 18 full session." 19 I assume that's talking about in that 20 agenda we saw earlier, there's going to be a full 21 session and there will be -- 22 A There's -- I'm sorry. 23 Q -- a section on talc where Dr. Belsito 24 give a presentation. Is that -- 25 A Correct. There's the two meetings, and</p>

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<p>1 then one or the other presents. So that's</p> <p>2 identifying Belsito as the team that will present</p> <p>3 or lead off.</p> <p>4 Q Okay. "Let me introduce this meeting's</p> <p>5 800-pound gorilla: Talc."</p> <p>6 Did I read that correctly?</p> <p>7 A Yes.</p> <p>8 Q "This is the first time you are seeing</p> <p>9 this. A scientific literature review was issued</p> <p>10 for public comment in August 2012. There is an</p> <p>11 old issue of asbestos in talc, but we think that</p> <p>12 talc as used in cosmetics is," parentheses, "as it</p> <p>13 well should be, asbestos-free." Right?</p> <p>14 A That's what it said.</p> <p>15 Q I read that correctly?</p> <p>16 A Yes.</p> <p>17 Q "Monice is putting it mildly when she</p> <p>18 says in her cover memo," quote: This safety</p> <p>19 assessment has generated a good deal of interest,</p> <p>20 end quote. "Be prepared to be interactive with</p> <p>21 the audience. EUROTALC offered to make a</p> <p>22 presentation."</p> <p>23 Who is EUROTALC?</p> <p>24 A It's a trade association in Europe that</p> <p>25 represents talc.</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q I didn't finish my question, but --</p> <p>3 A Sorry.</p> <p>4 Q A quite wordy anonymous source would not</p> <p>5 be as transparent as the CIR process seems to want</p> <p>6 to be, correct?</p> <p>7 A I think, as I said before, it's clear</p> <p>8 it's coming from industry. So...</p> <p>9 Q But what you don't know is who in</p> <p>10 industry, right?</p> <p>11 A That's correct.</p> <p>12 Q "Bill Kelly, panel book, 306 to 326.</p> <p>13 Kelly represents the Center for Regulatory</p> <p>14 Effectiveness, but I don't really know who they</p> <p>15 are."</p> <p>16 Bill Kelly is -- that's the letter we</p> <p>17 were talking about earlier, right?</p> <p>18 A Correct.</p> <p>19 Q Okay. He's the one representing CRE who</p> <p>20 is representing and presenting on behalf of</p> <p>21 Imerys, correct?</p> <p>22 MR. DONATH: Objection.</p> <p>23 THE WITNESS: I -- I mean, I presume</p> <p>24 he's presenting on behalf of Imerys only because I</p> <p>25 know they've presented on behalf of Imerys before.</p>
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<p>1 Q "They offered to make a presentation,</p> <p>2 but we did not see a particular need. Their input</p> <p>3 was clear, just for help to find the major stuff."</p> <p>4 Did I read that correctly or should it</p> <p>5 be read a different way? "Just for help to find</p> <p>6 the major stuff."</p> <p>7 A I -- I mean, it's a -- yeah -- oh, I</p> <p>8 mean, I think there's a colon at the end. It's a</p> <p>9 lead up to the next --</p> <p>10 Q Ah, now I see it. Okay.</p> <p>11 A -- the stuff that's --</p> <p>12 Q Okay. "Just for help to find the major</p> <p>13 stuff," colon.</p> <p>14 All right. So the first of the stuff</p> <p>15 is: "Anonymous input through the Council. Panel</p> <p>16 book, pages 106 to 305, quite wordy for an</p> <p>17 anonymous source."</p> <p>18 What does that mean?</p> <p>19 A Your guess is as good as mine.</p> <p>20 Apparently somebody submitted a lot of detail that</p> <p>21 came through the Council, so it is from industry.</p> <p>22 Q So not as transparent as the system --</p> <p>23 A It's from industry.</p> <p>24 MR. LOCKE: Objection -- objection to</p> <p>25 form.</p>	<p>1 BY MR. MEADOWS:</p> <p>2 Q "EUROTALC, panel book, pages 327 to 336.</p> <p>3 This is supplier input. Among the information</p> <p>4 that was provided by several submitters were</p> <p>5 newspaper articles. We did not include that info</p> <p>6 in the draft report. If you believe the data</p> <p>7 available on talc to be sufficient, then plan to</p> <p>8 issue a tentative report. Feel free to assert</p> <p>9 again that talc must be asbestos-free."</p> <p>10 We keep seeing that word, don't we,</p> <p>11 asbestos-free? This time with an exclamation</p> <p>12 point, right?</p> <p>13 A That's what it says.</p> <p>14 Q "The panel discussion will form the</p> <p>15 basis for the report discussion, so be thorough.</p> <p>16 If there are data needed to complete this safety</p> <p>17 assessment, then plan to issue an insufficient</p> <p>18 data announcement with a list of the needed data."</p> <p>19 Did I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q Okay.</p> <p>22 (Exhibit No. 105 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q All right. The next one I want to talk</p>

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<p>1 about is Exhibit 105.</p> <p>2 And lest I be accused of not providing</p> <p>3 the entire document, I am providing the entire</p> <p>4 document.</p> <p>5 Okay. So here's that word again --</p> <p>6 well, first, let's do this. Exhibit 105 has a</p> <p>7 Bates number PCPC 703, right?</p> <p>8 A Correct.</p> <p>9 Q Okay. And there's green. Right?</p> <p>10 A Yes.</p> <p>11 Q That's that color code system, right?</p> <p>12 A Right.</p> <p>13 Q And so this is the Safety Assessment of</p> <p>14 Talc As Used in Cosmetics, right?</p> <p>15 A Yes.</p> <p>16 Q So was this considered the draft report?</p> <p>17 Or what is this considered?</p> <p>18 A I would have to look on the next page,</p> <p>19 and it says it's the draft report.</p> <p>20 Q Okay. Okay. So you're ahead of me.</p> <p>21 This is the CIR letterhead, right?</p> <p>22 A Yes.</p> <p>23 Q "Memorandum to CIR Expert Panel Members</p> <p>24 and Liaisons," right?</p> <p>25 A Yes.</p>	<p>1 in December as well, right?</p> <p>2 A Yeah, and part of this is -- well, I</p> <p>3 shouldn't say it. I'm not sure what it is, but,</p> <p>4 yes, it is a big report.</p> <p>5 Q Mm-hmm.</p> <p>6 "As explained in the introduction,</p> <p>7 specifications for cosmetic talc state that they</p> <p>8 must be asbestos-free" --</p> <p>9 Here we are again, asbestos-free, right?</p> <p>10 A That's what it says.</p> <p>11 Q -- "and that it does not contain</p> <p>12 asbestiform fibers."</p> <p>13 Important, right?</p> <p>14 A Yes.</p> <p>15 Q "Because the purpose of this assessment</p> <p>16 is the safety of talc as used in cosmetics, to the</p> <p>17 best of our abilities, only studies addressing</p> <p>18 non-asbestiform talc were used."</p> <p>19 Have I read that correctly?</p> <p>20 A Yes.</p> <p>21 Q And then it goes on down, and it gives a</p> <p>22 list of the comments that have been received, I</p> <p>23 guess to date. So I guess there was a comment</p> <p>24 period; is that right?</p> <p>25 A There's always a comment period between</p>
Page 1017	Page 1019
<p>1 Q From Monice Fiume, senior scientific</p> <p>2 analyst provider. Date, November 16, 2012.</p> <p>3 "Subject: Safety Assessment of Talc As Used in</p> <p>4 Cosmetics."</p> <p>5 She says: "Enclosed is the draft report</p> <p>6 on the Safety Assessment of Talc As Used in</p> <p>7 Cosmetics. This is the first time the panel is</p> <p>8 seeing this document. The scientific literature</p> <p>9 review, which was a collaborative effort between</p> <p>10 me and Dr. Ivan Boyer, was issued on August 21,</p> <p>11 2012."</p> <p>12 So we are November 16, 2012, and the</p> <p>13 committee is going to meet on December 10 and 11,</p> <p>14 2012, to discuss and decide the -- how talc is</p> <p>15 going to be categorized, correct?</p> <p>16 A Yes.</p> <p>17 Q Okay. So we're a little less than a</p> <p>18 month, and the committee members have received</p> <p>19 this group of documents that's pretty extensive,</p> <p>20 no?</p> <p>21 A True.</p> <p>22 Q 340 pages.</p> <p>23 A That's what it looks like.</p> <p>24 Q And they have to review this in addition</p> <p>25 to other items that they're going to be reviewing</p>	<p>1 the different versions, yes.</p> <p>2 Q Okay. It looks like number 1 is PCPC</p> <p>3 submitted some comments?</p> <p>4 A On the scientific literature review, it</p> <p>5 looks like.</p> <p>6 Q Okay. Number 2 is a letter to Alan</p> <p>7 Andersen concerning scientific literature review</p> <p>8 through a Council anonymous, right?</p> <p>9 A Yes.</p> <p>10 Q So we don't know who that came from?</p> <p>11 A Correct.</p> <p>12 Q Bill Kelly, there he is, number 3. CRE</p> <p>13 on behalf of Imerys, right?</p> <p>14 A Yes.</p> <p>15 MR. DONATH: Objection to form.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q Number 4, comments regarding this all</p> <p>18 right., "Talc Is Used in Cosmetics," submitted by</p> <p>19 Michelle Wyart-Remy, EUROTALC, and Mark Ellis at</p> <p>20 IMA North America, right?</p> <p>21 A Yes.</p> <p>22 Q Okay. So that's the draft, right?</p> <p>23 A Yes.</p> <p>24 Q If we need to go back and take a look</p> <p>25 and see if anything changed from draft to final</p>

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<p>1 version, we've got the draft right here in our</p> <p>2 quick reference.</p> <p>3 A Yes.</p> <p>4 Q Okay. Now, so the next step in the</p> <p>5 process, I guess as far as the whole panel goes,</p> <p>6 is they met, right, in December?</p> <p>7 A Yes.</p> <p>8 (Exhibit No. 106 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. MEADOWS:</p> <p>11 Q And so the next document I want to look</p> <p>12 at is Exhibit 106.</p> <p>13 Okay. So Exhibit 106.</p> <p>14 (Counsel conferring.)</p> <p>15 BY MR. MEADOWS:</p> <p>16 Q Okay. Exhibit 106. Bates-numbered</p> <p>17 Plaintiff PCPC 212. Right?</p> <p>18 A Yes.</p> <p>19 Q And this is what?</p> <p>20 A This is obviously a document relating --</p> <p>21 okay. So this is still the December 10th meeting.</p> <p>22 Q Right. In Washington, D.C., right?</p> <p>23 A Yes.</p> <p>24 Q Okay. It's the main session or are we</p> <p>25 just on the first one?</p>	<p>1 A I think that's what it said, 13 reports.</p> <p>2 Q So they were discussing all 13 or 14 in</p> <p>3 the course of that day; is that correct?</p> <p>4 A Yes.</p> <p>5 MR. LOCKE: Objection to form.</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q And if we flip over to page 105 of 253,</p> <p>8 we see where a discussion regarding talc starts.</p> <p>9 Are you with me?</p> <p>10 A Yes.</p> <p>11 Q Dr. Belsito?</p> <p>12 A Yes.</p> <p>13 Q "Okay, good," is what he says. "So next</p> <p>14 we move on to talc. And this is a new report.</p> <p>15 The scientific literature review was just issued</p> <p>16 in August 2012. And over the many decades talc</p> <p>17 has gone under a number of -- sort of -- for lack</p> <p>18 of a better word, restrictions in terms of making</p> <p>19 sure there are no asbestiform particles, et</p> <p>20 cetera. And when I look at this document, I guess</p> <p>21 before I make any further comments, this is yours,</p> <p>22 Monice," and then he passes the microphone to</p> <p>23 Ms. Fiume, right?</p> <p>24 A Yes.</p> <p>25 Q Okay. And then there's an exchange,</p>
Page 1021	Page 1023
<p>1 A Right, I mean, I guess -- I'm just</p> <p>2 trying to figure out. So this is -- oh, so I</p> <p>3 suppose these are a transcript, I assume.</p> <p>4 Q I think you're right. I think you're</p> <p>5 right. That's the way I see it.</p> <p>6 And we can -- the first few pages tell</p> <p>7 us who the attendees are, right?</p> <p>8 A Yes.</p> <p>9 Q Liaison members, staff members, panel</p> <p>10 members, other attendees.</p> <p>11 David Goldstein, who is David Goldstein?</p> <p>12 A David Goldstein, I don't know.</p> <p>13 Q That would be on page 4 of 253.</p> <p>14 A I -- I don't know. I mean, anybody --</p> <p>15 again, it's open to the public, so he didn't --</p> <p>16 apparently didn't put his affiliation, or I assume</p> <p>17 it would be listed there.</p> <p>18 Q Okay. So this is the transcript of the</p> <p>19 entire meeting for the day, right?</p> <p>20 A That's what I would assume. It starts</p> <p>21 at 8:30, yeah.</p> <p>22 Q Starts at 8:30, and they're discussing</p> <p>23 not just talc but all the other ingredients -- I</p> <p>24 think -- did you say there's 13 that were being</p> <p>25 considered at this time?</p>	<p>1 and -- you point this out, it appears that this</p> <p>2 discussion of talc goes from page 105 to page 133,</p> <p>3 right?</p> <p>4 A Yes.</p> <p>5 Q Okay. So 28 pages of a 253-page</p> <p>6 transcript were devoted to discussing the safety</p> <p>7 of talc, right?</p> <p>8 A Yes.</p> <p>9 Q All right. Flip over to page 120, if</p> <p>10 you will, please, of the transcript.</p> <p>11 I guess this is about 15 pages in.</p> <p>12 A Okay.</p> <p>13 Q Right? Dr. Belsito says: "The</p> <p>14 discussion hasn't been developed yet, but, I mean,</p> <p>15 I think the whole issue of ovarian cancer, I'm not</p> <p>16 even sure that needs to be in the discussion. I</p> <p>17 mean, all the studies it did really seemed to get</p> <p>18 there -- it didn't really seem to get there even</p> <p>19 when applied to the perineal area."</p> <p>20 And that whole sort of -- Dr. Belsito is</p> <p>21 expressing he doesn't even think they need to be</p> <p>22 talking about this ovarian cancer issue because he</p> <p>23 doesn't see how in the world talc can ever get to</p> <p>24 the ovaries.</p> <p>25 MR. LOCKE: Objection.</p>

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<p style="text-align: right;">Page 1024</p> <p>1 BY MR. MEADOWS:</p> <p>2 Q That's what he's saying, right?</p> <p>3 MR. LOCKE: Objection to form.</p> <p>4 THE WITNESS: Something like that, yes.</p> <p>5 BY MR. MEADOWS:</p> <p>6 Q It goes on to say, Dr. Bergfeld speaks</p> <p>7 up: "But you spend a lot of time in the document</p> <p>8 on it, so you do need to bring it in -- bring it</p> <p>9 to an end somewhere."</p> <p>10 And then Dr. Belsito chimes in again:</p> <p>11 "Because if we have that, I think it's brought to</p> <p>12 an end in the document. You know, when you look</p> <p>13 at absorption of black whatever and everything</p> <p>14 else, it's not getting up there. So I don't know</p> <p>15 how the talc got there. Maybe it got there when</p> <p>16 they got an appendectomy in 1963 with talc</p> <p>17 containing gloves. I mean, I'm not sure. But</p> <p>18 applying it to the perineal area, all the data</p> <p>19 that is in the document would suggest it doesn't</p> <p>20 migrate from the vulva up to your ovary."</p> <p>21 Did I read that correctly?</p> <p>22 A Yes.</p> <p>23 Q Dr. Belsito, he's not a gynecologist, is</p> <p>24 he?</p> <p>25 A No.</p>	<p style="text-align: right;">Page 1026</p> <p>1 the report.</p> <p>2 BY MR. MEADOWS:</p> <p>3 Q "DR. BELSITO: Fine."</p> <p>4 "DR. LIEBLER: To the extent we simply</p> <p>5 say that the data are inconclusive, which I think</p> <p>6 is basically done.</p> <p>7 "DR. BELSITO: I don't think the data</p> <p>8 are inconclusive. The data are pretty conclusive</p> <p>9 that when you apply talc to the perineal area, it</p> <p>10 doesn't get to the ovary. You know, what's</p> <p>11 inconclusive is how the hell they got the ovary</p> <p>12 they were examining. I mean, I think that's</p> <p>13 inconclusive. But I think it's fairly conclusive</p> <p>14 that application of talc to the perineal area</p> <p>15 doesn't result in migration to the ovaries."</p> <p>16 Did I read that correctly?</p> <p>17 A Yes.</p> <p>18 Q Dr. Belsito was pretty doggone adamant</p> <p>19 this whole thing starts and stops with whether or</p> <p>20 not talc migrates to the ovaries, right?</p> <p>21 MR. LOCKE: Objection to form.</p> <p>22 THE WITNESS: I think what you read is</p> <p>23 correct, and that's his position, yes.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q Liebler says, We at least ought to talk</p>
<p style="text-align: right;">Page 1025</p> <p>1 Q What is he?</p> <p>2 A Dermatologist.</p> <p>3 Q Dr. Liebler chimes in. "So we've got, I</p> <p>4 think, over four full pages on ovarian cancer</p> <p>5 epidemiology and talc in this report. So we've</p> <p>6 got to at least mention it in the discussion."</p> <p>7 That's what you say, right?</p> <p>8 MR. LOCKE: Objection to form.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Talc epidemiology, ovarian cancer</p> <p>11 epidemiology is at least mentioned in the</p> <p>12 discussion, isn't it?</p> <p>13 MR. LOCKE: Objection to form.</p> <p>14 THE WITNESS: I -- I think it's</p> <p>15 discussed in the report.</p> <p>16 BY MR. MEADOWS:</p> <p>17 Q Yeah, that's what you said earlier,</p> <p>18 right?</p> <p>19 A Yes.</p> <p>20 Q And that's what Liebler was saying, we</p> <p>21 need to -- even if we're going to say it can't</p> <p>22 there, we at least need to talk about it a little</p> <p>23 bit, right?</p> <p>24 MR. LOCKE: Objection to form.</p> <p>25 THE WITNESS: I said it's discussed in</p>	<p style="text-align: right;">Page 1027</p> <p>1 about epidemiology. Belsito begrudgingly says,</p> <p>2 Fine. And the discussion ends with the data are</p> <p>3 inconclusive, right?</p> <p>4 MR. LOCKE: Objection to form.</p> <p>5 THE WITNESS: That's what Dr. Liebler</p> <p>6 says, yes.</p> <p>7 BY MR. MEADOWS:</p> <p>8 Q And this is that same package of</p> <p>9 information they just got three weeks earlier,</p> <p>10 right?</p> <p>11 A Well, there's -- it's preceded by the</p> <p>12 scientific literature review.</p> <p>13 Q Do you get the impression that these</p> <p>14 guys have been reviewing that literature for the</p> <p>15 last six months?</p> <p>16 MR. LOCKE: Objection to form.</p> <p>17 THE WITNESS: Not in this conversation,</p> <p>18 no.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q Yeah.</p> <p>21 (Exhibit No. 107 was marked for</p> <p>22 identification.)</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q Okay. The next document I'd like to</p> <p>25 talk about is Exhibit 107. And it's Bates stamped</p>

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<p>1 Pltf_PCPC 211.</p> <p>2 A Yes.</p> <p>3 Q And what -- this one seen is titled</p> <p>4 "Breakout Session," and I guess it was the same</p> <p>5 day, wasn't it?</p> <p>6 A So what I'm guessing is this is the</p> <p>7 other team.</p> <p>8 Q Tell me about that. I'm not sure I</p> <p>9 understood there to be another team.</p> <p>10 A That's what I was saying, how the way</p> <p>11 this process works is on the first day they split</p> <p>12 into two teams. There's eight CIR members plus</p> <p>13 the chairperson, and they split into two teams and</p> <p>14 discuss the ingredients.</p> <p>15 And then the second day, they get</p> <p>16 together, and each team brings their conclusion</p> <p>17 and points they want to talk about. And that was</p> <p>18 where we were saying like, for example, that one</p> <p>19 person will lead on an ingredient, and that will</p> <p>20 be, basically, one team will lead, and then the</p> <p>21 second team will lead on other -- lead on</p> <p>22 different ingredients.</p> <p>23 Q Okay. I'm not --</p> <p>24 A So what you were looking at before was a</p> <p>25 transcript from the team meeting -- one of the</p>	<p>1 What does that mean?</p> <p>2 A As we were talking about before,</p> <p>3 ingredients containing -- reports containing</p> <p>4 multiple ingredients, that's what he's saying,</p> <p>5 that this is just talc, no -- no other</p> <p>6 ingredients.</p> <p>7 Q "So that makes it simple, although it</p> <p>8 didn't reduce, yeah. So, Tom, it seems like to me</p> <p>9 when I read it, there's issues of obviously the</p> <p>10 cancer and whether there's asbestos or not. Is</p> <p>11 that the reason, the concern? So, would you</p> <p>12 comment about that, Tom? How do you want to</p> <p>13 proceed with this? Supposedly cosmetic grade is</p> <p>14 asbestos-free."</p> <p>15 There we go again with asbestos-free,</p> <p>16 right?</p> <p>17 A Yeah.</p> <p>18 Q Tom, I guess, was Dr. Slaga?</p> <p>19 A Yes.</p> <p>20 Q So Dr. Slaga says: "Well, that is as it</p> <p>21 states very clearly in here. The cosmetic grade</p> <p>22 now doesn't have the asbestos. It's asbestos-</p> <p>23 free, and it does not contain asbestiform fibers."</p> <p>24 Did I read that correctly?</p> <p>25 A Yes.</p>
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<p>1 team meetings. This is a transcript I think from</p> <p>2 the other team meeting.</p> <p>3 Q And so these are team -- these are two</p> <p>4 teams that -- that are ultimately ones that will</p> <p>5 author the -- the study or -- yeah, the study or</p> <p>6 they different -- is the second team completely</p> <p>7 different?</p> <p>8 A The expert panel is split into two</p> <p>9 teams, so yes.</p> <p>10 Q Okay. Okay. Now, I think I understand</p> <p>11 now, and maybe I'll understand better after we</p> <p>12 look at this.</p> <p>13 Okay. So this is called the "Breakout</p> <p>14 Session." And it appears to me that the talc</p> <p>15 discussion starts on page 136 of 151.</p> <p>16 Does that look about right to you?</p> <p>17 A Yes.</p> <p>18 Q It looks like it starts at the top. It</p> <p>19 says the word "talc" near the top.</p> <p>20 A Yes.</p> <p>21 Q It's the first time we've seen this?</p> <p>22 A Yes.</p> <p>23 Q It's a thick report. "Thanks, Monice.</p> <p>24 So we don't have to worry about a lot of add-ons</p> <p>25 on this one, do we? It's talc."</p>	<p>1 Q And then you flip over to the next page,</p> <p>2 Tom Slaga continues. If you go down -- I guess</p> <p>3 it's the second sentence of the first full</p> <p>4 paragraph: "It had some little problems, but a</p> <p>5 number of people, in reviewing those suggested</p> <p>6 they really were quite the artifact, and that to</p> <p>7 me, and the other aspects, it's related to ovarian</p> <p>8 cancer, which the data really is not -- you can't</p> <p>9 really -- it's associated. There's not really</p> <p>10 studies to really say it has a relationship, a</p> <p>11 causative relationship to ovarian cancer."</p> <p>12 A Hang on a sec.</p> <p>13 MR. LOCKE: Objection. You've omitted</p> <p>14 the preceding --</p> <p>15 THE WITNESS: Yeah, this --</p> <p>16 MR. MEADOWS: Okay. We'll read the</p> <p>17 whole thing.</p> <p>18 THE WITNESS: Because it's switching</p> <p>19 topics mid -- it's talking about inhalation, and</p> <p>20 then it's going to ovarian.</p> <p>21 BY MR. MEADOWS:</p> <p>22 Q Okay. "DR. SLAGA: Well, that is, as it</p> <p>23 states very clearly in here, the cosmetic grade</p> <p>24 now doesn't have asbestos. It's asbestos-free,</p> <p>25 and it does not contain the asbestiform fibers.</p>

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<p>1 In the past you just used to get in a lot of</p> <p>2 trouble, but still there's a number of reports.</p> <p>3 EPA did inhalation studies, which were negative,</p> <p>4 and then NTP, which was also negative. But in</p> <p>5 different other routes of administration has some</p> <p>6 limited carcinogenicity, but still nothing really,</p> <p>7 you know. The number of adrenal tumors in female</p> <p>8 rats and low response.</p> <p>9 "But in every case it was extensively</p> <p>10 high saturating amounts of talc, which seem to be</p> <p>11 the high end of the concentration they use. It</p> <p>12 had some little problems, but a number of people</p> <p>13 in reviewing those suggested that they really were</p> <p>14 quite the artifact and that to me, in the other</p> <p>15 aspects it's related to ovarian cancer, which the</p> <p>16 data's really not -- you can't really -- it's</p> <p>17 associate -- it's associated. There's not really</p> <p>18 studies to really say it has a relationship, a</p> <p>19 causative relationship to ovarian cancer."</p> <p>20 Then you go down, "DR. SHANK: I agree.</p> <p>21 If topical application of talc leads to cancer of</p> <p>22 the ovary, why does it not lead to cancer of the</p> <p>23 cervix and cancer of the uterus? I think this</p> <p>24 ovarian cancer situation is not a real problem."</p> <p>25 That's what he said, right?</p>	<p>1 MR. LOCKE: We've been going for an hour</p> <p>2 and 50 minutes. Does -- I'm happy to keep going.</p> <p>3 I ask the witness and the court reporter and the</p> <p>4 videographer.</p> <p>5 MR. MEADOWS: Take a break? Okay.</p> <p>6 Let's take a break.</p> <p>7 THE VIDEOGRAPHER: The time is 3:03 p.m.</p> <p>8 We're going off the record.</p> <p>9 (Recess.)</p> <p>10 THE VIDEOGRAPHER: The time is 3:16</p> <p>11 p.m., and we're back on the record.</p> <p>12 (Exhibit No. 108 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Dr. Loretz, the next document I'd like</p> <p>16 to discuss what I've marked as Exhibit 108.</p> <p>17 And, first of all, we're talking about</p> <p>18 -- we're starting at PCPC 213, correct?</p> <p>19 A Yes.</p> <p>20 Q Okay. And so this one is entitled</p> <p>21 "125th Cosmetic Ingredient Review Expert Panel</p> <p>22 Meeting" on Tuesday, December 11th, in Washington,</p> <p>23 D.C., correct?</p> <p>24 A Yes.</p> <p>25 Q So this would be the day after the</p>
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<p>1 A Yes.</p> <p>2 Q Dr. Slaga said: "Right."</p> <p>3 THE REPORTER: I'm sorry, what did you</p> <p>4 say? I can't hear.</p> <p>5 MR. MEADOWS: Dr. Slaga said: "Right."</p> <p>6 BY MR. MEADOWS:</p> <p>7 Q And so this particular discussion about</p> <p>8 the safety of talc takes up a grand total of four</p> <p>9 pages, right?</p> <p>10 MR. LOCKE: Objection to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Not exactly an extensive and robust</p> <p>14 discussion of the science, would you say?</p> <p>15 MR. LOCKE: Objection to form and beyond</p> <p>16 the scope.</p> <p>17 THE WITNESS: It was -- that was a</p> <p>18 short discussion. I think the report is more</p> <p>19 meaningful.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q The report is more meaningful than the</p> <p>22 discussion?</p> <p>23 A Well, I mean, I think you also have to</p> <p>24 look at what the report says and --</p> <p>25 Q Well --</p>	<p>1 meetings which transcripts we went through just</p> <p>2 moments ago, correct?</p> <p>3 A The team meetings, right.</p> <p>4 Q Okay. And so there were two meetings on</p> <p>5 December 10th of 2012, where two groups of the</p> <p>6 panel met and discussed the safety of talc,</p> <p>7 correct?</p> <p>8 A Correct.</p> <p>9 Q Okay. And the one particular meeting,</p> <p>10 there was a discussion that went on for about 28</p> <p>11 pages, right?</p> <p>12 A Yes.</p> <p>13 Q And then the other was about a four-page</p> <p>14 discussion, correct?</p> <p>15 A Correct.</p> <p>16 Q Okay. And so now we're at Day 2 of the</p> <p>17 Cosmetic Ingredient Review Panel Meeting. Now</p> <p>18 what -- what happens on Day 2?</p> <p>19 A So then Day 2 is when both of the teams</p> <p>20 get together, and as I say, there's a designated</p> <p>21 lead for each ingredient, and they start off by</p> <p>22 stating their conclusions and what data they're</p> <p>23 looking for, et cetera, and then the other team</p> <p>24 chimes in with their opinion, and they discuss it</p> <p>25 and come to a final conclusion between the -- both</p>

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<p style="text-align: right;">Page 1036</p> <p>1 teams.</p> <p>2 Q Okay. So we're going to take a look at</p> <p>3 that, but just a point of reference, from what I</p> <p>4 can figure, the talc discussion starts on page 47</p> <p>5 of 75.</p> <p>6 Are you with me?</p> <p>7 A I am. I'm on 47.</p> <p>8 Q It actually starts at the very bottom of</p> <p>9 47. It says: "Then moving on to a green</p> <p>10 document, Dr. Belsito on talc." Right?</p> <p>11 A Yes.</p> <p>12 Q Okay. And so Dr. Belsito, whom we heard</p> <p>13 from earlier, right?</p> <p>14 A Yes.</p> <p>15 Q He's the one who was pretty adamant that</p> <p>16 talc just cannot get to the ovaries, right?</p> <p>17 MR. LOCKE: Objection to form.</p> <p>18 THE WITNESS: He said that, yes.</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q He doesn't know how the hell it gets</p> <p>21 there, in his words, but he knows it doesn't get</p> <p>22 there, right?</p> <p>23 MR. LOCKE: Objection to form.</p> <p>24 THE WITNESS: He -- yes.</p> <p>25 BY MR. MEADOWS:</p>	<p style="text-align: right;">Page 1038</p> <p>1 to ovarian cancer is totally unclear, but</p> <p>2 certainly doesn't seem to be a vaginal absorption</p> <p>3 into the ovaries from perineal application."</p> <p>4 Right?</p> <p>5 A That's what it says.</p> <p>6 Q He's -- he's pretty adamant about this,</p> <p>7 isn't he?</p> <p>8 A It seems to be that way.</p> <p>9 Q Yeah. It doesn't seem like he needs any</p> <p>10 advice from a gynecologist, does it?</p> <p>11 MR. LOCKE: Objection to form.</p> <p>12 THE WITNESS: Well, he has read the</p> <p>13 report. So...</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Yeah. Doesn't seem like he needs any</p> <p>16 advice from somebody who specializes in the female</p> <p>17 anatomy, does it?</p> <p>18 MR. LOCKE: Objection to form and beyond</p> <p>19 the scope.</p> <p>20 THE WITNESS: He's not asking for any,</p> <p>21 no.</p> <p>22 BY MR. MEADOWS:</p> <p>23 Q Yeah. I don't see -- in reviewing these</p> <p>24 transcripts, I didn't see where anybody on the</p> <p>25 panel asked for any consultation with an expert in</p>
<p style="text-align: right;">Page 1037</p> <p>1 Q "DR. BELSITO: Yes, this is the first</p> <p>2 time we're seeing this document."</p> <p>3 He's referring to a document I guess</p> <p>4 they received three weeks earlier, right?</p> <p>5 A Yes.</p> <p>6 Q And that would be the draft report,</p> <p>7 right?</p> <p>8 A Yes.</p> <p>9 Q "There was a considerable amount of</p> <p>10 information. There are some data that we've been</p> <p>11 told can be further incorporated into the</p> <p>12 document, and there are some minor editorial</p> <p>13 changes. But overall, we felt we could go safe as</p> <p>14 used with some very important discussion points."</p> <p>15 "DR. MARKS: Second."</p> <p>16 Right?</p> <p>17 A Yes.</p> <p>18 Q "DR. BERGFELD: All right. Can we have</p> <p>19 the discussion points, please.</p> <p>20 "DR. BELSITO: Impurities, that they not</p> <p>21 contain at best foreign materials."</p> <p>22 Do you have any idea what he's talking</p> <p>23 about there?</p> <p>24 A No, not specifically.</p> <p>25 Q "We felt that the mechanism for any link</p>	<p style="text-align: right;">Page 1039</p> <p>1 the female reproductive system, did you?</p> <p>2 A No.</p> <p>3 Q They certainly could have asked for</p> <p>4 that, right?</p> <p>5 A They could.</p> <p>6 Q So this discussion of the safety of talc</p> <p>7 goes all the way over to page 50. Do you see</p> <p>8 that?</p> <p>9 MR. LOCKE: For the record, counsel</p> <p>10 omitted a portion of what -- more than half of</p> <p>11 what Dr. Belsito said in that paragraph that was</p> <p>12 read.</p> <p>13 MR. MEADOWS: Thank you.</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q So back to my question.</p> <p>16 A Yes. It goes to page 50.</p> <p>17 Q Okay. So it started at the bottom of 47</p> <p>18 of a 75-page document, and it ended at the bottom</p> <p>19 of page 50 or thereabouts of a 75-page transcript.</p> <p>20 Correct?</p> <p>21 A Yes.</p> <p>22 Q So the entire panel, when they got</p> <p>23 together, they discussed it for three pages.</p> <p>24 Right?</p> <p>25 A Yes.</p>

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<p style="text-align: right;">Page 1040</p> <p>1 Q And most of that was Dr. Belsito, right?</p> <p>2 A Yes.</p> <p>3 Q In particular, Dr. Belsito on talc</p> <p>4 migration in the female anatomy, right?</p> <p>5 MR. LOCKE: Objection. Form.</p> <p>6 THE WITNESS: Certainly some of that is</p> <p>7 that, yes.</p> <p>8 BY MR. MEADOWS:</p> <p>9 Q And with that, talc was declared safe,</p> <p>10 right?</p> <p>11 A They moved on to the next report level,</p> <p>12 yes, with that conclusion, correct.</p> <p>13 Q Because it wasn't going to turn around</p> <p>14 after that, was it?</p> <p>15 MR. LOCKE: Objection to form.</p> <p>16 THE WITNESS: It --</p> <p>17 MR. LOCKE: Mischaracterizes</p> <p>18 information.</p> <p>19 THE WITNESS: It can, but it didn't.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q At what point can it get turned to</p> <p>22 unsafe or something other than safe after they --</p> <p>23 this panel declares that it's safe?</p> <p>24 A It can. It doesn't happen frequently.</p> <p>25 I mean, they're going --</p>	<p style="text-align: right;">Page 1042</p> <p>1 maybe that will help me understand where we are in</p> <p>2 the process.</p> <p>3 A So this is the first -- the first</p> <p>4 step -- the first thing that comes out is called</p> <p>5 the scientific literature review. So this is what</p> <p>6 the -- this is the pulling together of the</p> <p>7 literature by CIR staff.</p> <p>8 Q Mm-hmm.</p> <p>9 A So this is the first step -- the first</p> <p>10 document in the process.</p> <p>11 Q Okay. So this is rewinding several</p> <p>12 months, right, from where we were on the</p> <p>13 transcripts?</p> <p>14 A Correct. And you can see Alan Andersen</p> <p>15 was the director, so that tells you when he left.</p> <p>16 Q Okay. So he left shortly after this.</p> <p>17 A Right.</p> <p>18 Q Okay. And so would this have gone to</p> <p>19 the executive -- or, excuse me, the expert panel?</p> <p>20 A Yes.</p> <p>21 Q And this is what they would have</p> <p>22 considered over the months leading up to their</p> <p>23 receiving the first draft of the report in</p> <p>24 November?</p> <p>25 A I think that's fair to say, yes.</p>
<p style="text-align: right;">Page 1041</p> <p>1 Q Okay. At what point?</p> <p>2 A Well, they discuss it again. So...</p> <p>3 Q When -- when did they discuss this</p> <p>4 again?</p> <p>5 A So that would have been -- the next</p> <p>6 would be the draft, there would be another report</p> <p>7 after this.</p> <p>8 Q So when would they have discussed it?</p> <p>9 A The next meeting or two meetings out.</p> <p>10 Q Okay. Are you aware of any further</p> <p>11 discussion?</p> <p>12 A Two meetings out or, as I say,</p> <p>13 whenever -- they discussed it one more time before</p> <p>14 it goes final, yes.</p> <p>15 Q All right. Let's look at the next</p> <p>16 document.</p> <p>17 (Exhibit No. 109 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. MEADOWS:</p> <p>20 Q I show you what we've marked as</p> <p>21 Exhibit 109.</p> <p>22 I got it up here on the screen. It's</p> <p>23 Bates Pltf_IMERYYS 1120. Right?</p> <p>24 A Yes.</p> <p>25 Q Okay. And so tell me what this is, and</p>	<p style="text-align: right;">Page 1043</p> <p>1 Q Okay. All right.</p> <p>2 (Exhibit No. 110 was marked for</p> <p>3 identification.)</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q So the next thing I want to look at is</p> <p>6 what we've marked as Exhibit 110. Do you see</p> <p>7 that?</p> <p>8 You recognize that, Dr. Loretz?</p> <p>9 A This is the published report.</p> <p>10 Q Okay. So this is what ultimately came</p> <p>11 out from the -- the panel transcripts that we saw,</p> <p>12 the draft report that we saw, the SLR that we saw,</p> <p>13 ultimately it came -- all came together in this</p> <p>14 particular document, correct?</p> <p>15 MR. LOCKE: Objection. Mischaracterizes</p> <p>16 testimony. It omits a key portion.</p> <p>17 MR. MEADOWS: Tell me what key portion I</p> <p>18 missed.</p> <p>19 THE WITNESS: Well, after the --</p> <p>20 MR. LOCKE: Well --</p> <p>21 MR. MEADOWS: I'm asking her.</p> <p>22 MR. LOCKE: Okay.</p> <p>23 THE WITNESS: After the draft report,</p> <p>24 there's a final report, and then that's turned</p> <p>25 into a publication.</p>

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<p>1 BY MR. MEADOWS:</p> <p>2 Q Okay. So the final report, is that</p> <p>3 something you and I need to talk about right now?</p> <p>4 Is there something in there that you feel like is</p> <p>5 important before we move to --</p> <p>6 A I guess just to say there was another</p> <p>7 review time, that -- I mean, they looked at the</p> <p>8 final report before it was finalized.</p> <p>9 Q Okay. And so when the file report came</p> <p>10 out, when would that have been?</p> <p>11 A I think -- so it would have been in</p> <p>12 2013.</p> <p>13 Q Okay. And it would have been reviewed</p> <p>14 by whom?</p> <p>15 A Well, there would be one more step in</p> <p>16 the process of -- of the report that would be</p> <p>17 reviewed again by the two teams and again by the</p> <p>18 CIR expert panel.</p> <p>19 Q So after they met in December of 2012</p> <p>20 and said that talc is safe, then the next step was</p> <p>21 a final report was put together and distributed</p> <p>22 amongst the members in early 2013?</p> <p>23 A Yeah, I think they call it a final</p> <p>24 tentative report, something like that.</p> <p>25 Q Okay.</p>	<p>1 Q Okay. And when the -- when the draft</p> <p>2 report was issued, did it -- did it only go to the</p> <p>3 panel members or did it also go to members of</p> <p>4 PCPC, meaning industry?</p> <p>5 A The next version of the report -- again,</p> <p>6 it's all public, so it would come out to -- I</p> <p>7 mean, they would send it, of course, to the panel</p> <p>8 members, but it would be published on their</p> <p>9 website.</p> <p>10 Q Okay. So anybody can look at it.</p> <p>11 A Exactly.</p> <p>12 Q And can anybody comment on it?</p> <p>13 A Yeah, there's a -- and there's a --</p> <p>14 there's a comment period, always. I mean, that's</p> <p>15 the normal process.</p> <p>16 Q Okay. All right.</p> <p>17 All right. Turning back to Exhibit 110.</p> <p>18 You recognize that as the document that was</p> <p>19 ultimately published reflect -- reflecting the</p> <p>20 findings of the CIR concerning the Safety</p> <p>21 Assessment of Talc As Used in Cosmetics?</p> <p>22 A Okay. Yes.</p> <p>23 Q Okay. Now, there's a couple of parts of</p> <p>24 in that I want to take a look at. And in</p> <p>25 particular, I want to turn to page 122S.</p>
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<p>1 A Don't quote me on that, but it's -- it's</p> <p>2 the next step, yes.</p> <p>3 Q And is it -- is it published in any way</p> <p>4 or is it just kept amongst the members as they</p> <p>5 review it?</p> <p>6 A No, it's public.</p> <p>7 Q Okay.</p> <p>8 A It's -- there's another meeting where</p> <p>9 they talk again.</p> <p>10 Q All right. And when was that meeting?</p> <p>11 A I don't know. It had to be in 2013, I'm</p> <p>12 sure.</p> <p>13 Q Are there transcripts of that meeting?</p> <p>14 A Yes.</p> <p>15 Q And the entire panel would meet?</p> <p>16 A Yep. Yes. Exactly the same way. It's</p> <p>17 just a -- it's like when you talk about that they</p> <p>18 looked at 13 reports, okay, so this is the same</p> <p>19 thing, and now they're looking at that talc is now</p> <p>20 in a different -- further along in the process.</p> <p>21 Q Are you aware of any substantial changes</p> <p>22 between the final report and what was submitted</p> <p>23 for publication?</p> <p>24 A I've never done that assessment, but no.</p> <p>25 But I would not expect there to be any.</p>	<p>1 Are you there?</p> <p>2 A Yes.</p> <p>3 Q Okay. Now, this is under the discussion</p> <p>4 section, right?</p> <p>5 A Okay.</p> <p>6 Q And starting with the second paragraph.</p> <p>7 A Okay.</p> <p>8 Q "During its deliberations, the panel</p> <p>9 discussed a 2012 FDA study in which talc samples</p> <p>10 and talc-containing products were analyzed for the</p> <p>11 presence of asbestos. Of the nine companies</p> <p>12 contacted, four supplied data to the FDA. No</p> <p>13 asbestos was detected in any of the talc samples</p> <p>14 or the talc-containing products.</p> <p>15 "The panel requested clarification of</p> <p>16 the analytical methods used to confirm lack of</p> <p>17 significant asbestiform amphibole content. In</p> <p>18 response to this request, the panel was advised</p> <p>19 that talc is certified to be asbestos-free" --</p> <p>20 there's that phrase again, right?</p> <p>21 A Yes.</p> <p>22 Q -- "and their mines are monitored for</p> <p>23 asbestos concentration."</p> <p>24 Did I read that correctly?</p> <p>25 A Yes.</p>

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<p>1 Q Asbestos-free, right?</p> <p>2 A Although I note the conclusion is that</p> <p>3 it's "no detectable."</p> <p>4 Q Well --</p> <p>5 A That's what the abstract says.</p> <p>6 Q Yeah.</p> <p>7 (Exhibit No. 111 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q So let's take a look at what I've marked</p> <p>11 as Exhibit 111.</p> <p>12 See at the bottom where I've marked it</p> <p>13 as Exhibit 111? It's Bates number JNJ 637879.</p> <p>14 A Yes.</p> <p>15 Q And it's from a magazine that I call the</p> <p>16 Rose Sheet. Have you ever heard of that?</p> <p>17 A Yes.</p> <p>18 Q Okay. So the Rose Sheet had an article</p> <p>19 about this topic. It's entitled "FDA. No</p> <p>20 Asbestos Found in Talc Products Sampled But</p> <p>21 Results Limited."</p> <p>22 Did I read that correctly?</p> <p>23 A Yes.</p> <p>24 Q And this is dated March 2012, right?</p> <p>25 A Yes.</p>	<p>1 Q Is that taken into account anywhere in</p> <p>2 the CIR's review of talc?</p> <p>3 A I don't know. I --</p> <p>4 Q Well, certainly, the portion that we</p> <p>5 read just moments ago indicates that this panel is</p> <p>6 under the impression that talc as found in</p> <p>7 cosmetics that they're evaluating is</p> <p>8 asbestos-free, right?</p> <p>9 MR. LOCKE: Objection. Mischaracterizes</p> <p>10 the document.</p> <p>11 THE WITNESS: Yeah, I -- I mean, this --</p> <p>12 FDA states conservatively as a public health agent</p> <p>13 -- I mean, as a government agency, that they did a</p> <p>14 sampling, but because it wasn't as totally</p> <p>15 exhaustive, they're not saying that there's no</p> <p>16 problem at all.</p> <p>17 So I don't think that's inconsistent</p> <p>18 with -- with the CIR not identifying an asbestos</p> <p>19 problem.</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q Well, now the CIR, as you pointed out,</p> <p>22 went through multiple rounds of looking at this</p> <p>23 draft, right?</p> <p>24 A Yes.</p> <p>25 Q They studied every word before they</p>
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<p>1 Q So which would have been before the CIR</p> <p>2 talc review was done, right?</p> <p>3 A Correct.</p> <p>4 Q Okay. And so the executive summary</p> <p>5 says: "Following reports of asbestos in talc and</p> <p>6 talc-containing products overseas, FDA conducted a</p> <p>7 survey of suppliers and products on the U.S.</p> <p>8 market, finding no detectable levels of asbestos.</p> <p>9 The FDA has released the results of a review</p> <p>10 screening for asbestos particles in talc and</p> <p>11 talc-containing cosmetic products, and finding no</p> <p>12 detectable levels of the carcinogen in supplier</p> <p>13 samples or products on the U.S. market. The</p> <p>14 Agency notes, however, that hard conclusions</p> <p>15 cannot be drawn due to the limited number of</p> <p>16 supplier samples and products tested.</p> <p>17 "For these reasons, while FDA finds</p> <p>18 these results informative, they do not prove that</p> <p>19 most or all talc or talc-containing cosmetic</p> <p>20 products currently marketed in the United States</p> <p>21 are likely to be free of asbestos contamination,</p> <p>22 the Agency says in a March 1 update to a page on</p> <p>23 its website regarding talc in cosmetics."</p> <p>24 Did I read that correctly?</p> <p>25 A Yes.</p>	<p>1 decided how this article would be written, right?</p> <p>2 A Yes. It goes through multiple rounds.</p> <p>3 Q And they decided to put the phrase</p> <p>4 "asbestos-free" in here, right?</p> <p>5 A And if I look at the -- I -- they did,</p> <p>6 but in the abstract, the conclusion is they say</p> <p>7 "no detectable asbestos."</p> <p>8 Q And they chose to not mention anything</p> <p>9 about the fact that the FDA has said: "For these</p> <p>10 reasons, while FDA finds these results</p> <p>11 informative, they do not prove that most or all</p> <p>12 talc or talc-containing cosmetic products</p> <p>13 currently marketed in the United States are likely</p> <p>14 to be free of asbestos contamination."</p> <p>15 That's not mentioned anywhere in the CIR</p> <p>16 report, is it?</p> <p>17 A Well, I'd have to look at exactly what</p> <p>18 the CIR report says about this, but FDA is -- is</p> <p>19 not saying that they expect to find asbestos.</p> <p>20 They're just saying this is a limited enough</p> <p>21 survey that they can't --</p> <p>22 Q Well, the CIR is certainly under the</p> <p>23 impression, or otherwise they wouldn't say as</p> <p>24 much, that talc is asbestos-free, right?</p> <p>25 MR. LOCKE: Objection to form. What</p>

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<p>1 you're pointing out refers to the panel was 2 advised that. 3 THE WITNESS: And they use the phrase 4 "no detectable asbestos." They don't -- in the -- 5 in their conclusion. And this does not say that 6 FDA thinks that there is asbestos. It just says 7 we don't think we tested enough to come to a 8 definitive conclusion about all products. 9 BY MR. MEADOWS: 10 Q Does the CIR report at any point in time 11 say, We don't believe it, we just do not believe 12 that talc is asbestos-free? 13 A This's not what FDA says either. 14 Q I'm asking you about the CIR report. 15 A I would have to look at -- 16 Q Does the CIR report -- 17 A -- what the words are here. 18 Q -- ever say, They tell us it's 19 asbestos-free, but we don't believe it? 20 A They say that the conclusion is that -- 21 I -- I can't tell you what it is without looking, 22 but they refer to there being no detectable 23 asbest- -- asbestos. 24 Q There's a difference between no 25 detectable level and asbestos-free, right?</p>	<p>1 THE WITNESS: That's not the conclusion 2 of the CIR report and the abstract. 3 BY MR. MEADOWS: 4 Q So you're saying that the CIR report 5 recognized the fact that the FDA had pointed out 6 in the Rose Sheet that there's no -- "For these 7 reasons, while FDA finds these results 8 informative, they do not prove that most or talc 9 or talc-containing cosmetic products currently 10 marketed in the United States are likely to be 11 free of asbestos contamination." 12 MR. LOCKE: Objection to form, to the 13 extent you're saying the FDA does anything with 14 the Rose Sheet. 15 THE WITNESS: FDA is just saying that 16 they're acknowledging that it is not a 17 comprehensive -- that they -- they didn't look at 18 all products. They're not saying that everything 19 is free, that they have not proven that. They're 20 not saying that they see a problem. In fact, 21 they're saying that they -- in their assessment 22 that they did, they found no problems. 23 BY MR. MEADOWS: 24 Q Well, I mean, to be safe, and -- and I 25 think we talked about how earlier that there are</p>
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<p>1 A The conclusion is, is no detectable 2 asbestos, and then they talk about others saying 3 asbestos-free. 4 Q And the reason that those phrases are 5 important to you is because "asbestos-free" would 6 mean, We can guarantee you there's no asbestos in 7 this product; whereas "no detectable level" would 8 mean, We're not so sure we can say that it's not 9 asbestos -- that's it asbestos-free, right? 10 A The conclusion of the report is that 11 there is no detectable asbestos. 12 MR. LOCKE: The very paragraph you've 13 got on the screen says that. 14 MR. MEADOWS: Counsel, you'll get an 15 opportunity to question if you'd like. 16 MR. LOCKE: Well, you're just asking 17 something that doesn't make sense based on what 18 you're showing the jury. 19 MR. MEADOWS: And I object and move to 20 strike your commentary. 21 BY MR. MEADOWS: 22 Q We've seen numerous documents today, 23 PCPC, CIR documents, that talk about cosmetic talc 24 being, quote/unquote, asbestos-free, haven't we? 25 MR. LOCKE: Objection to form.</p>	<p>1 documents that talk about how the PCPC is 2 interested in public safety, right? 3 A Yes. 4 Q So to be on the safe side, wouldn't it 5 have been wise to include in the CIR report that, 6 you know, We're hearing from the FDA that we can't 7 guarantee that all talc is not asbestos-free? 8 MR. LOCKE: Objection to form. 9 THE WITNESS: I don't think that's what 10 the FDA is saying. 11 And again, I would go back to the 12 abstract, which is what you would read for their 13 conclusion, is -- refers to "no detectable 14 asbest- -- asbestos." 15 BY MR. MEADOWS: 16 Q Is there an evaluation within the CIR 17 report where the CIR takes into account the 18 possibility that there is asbestos in -- in the 19 talc that they're -- that they're discussing? 20 A They look at the issue of asbestos and 21 talk about what they have -- information that they 22 have, and that they are not aware of any asbestos 23 contamination. 24 Q Going back to the -- Exhibit 110, the 25 section of the CIR report, pages -- let's see --</p>

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<p>1 starting on page 67, the bottom section entitled</p> <p>2 "Mineralogy and Chemistry."</p> <p>3 Do you see where I'm talking about?</p> <p>4 A No.</p> <p>5 Q Second --</p> <p>6 A Okay.</p> <p>7 Q Are you with me? Okay.</p> <p>8 And it goes through I think to page 70</p> <p>9 maybe, where it ends at "Use." Do you see that?</p> <p>10 A Yes.</p> <p>11 Q Do you know who wrote that section?</p> <p>12 A No.</p> <p>13 Q Is there any way to find out who wrote</p> <p>14 that section?</p> <p>15 A I assume CIR did. CIR staff.</p> <p>16 Q CIR staff?</p> <p>17 A That's what I would assume.</p> <p>18 Q Well, is there any way to find out for</p> <p>19 sure that you know of?</p> <p>20 A I guess you would need to ask CIR.</p> <p>21 Q All right. Okay. Going back to</p> <p>22 Exhibit 110. And I want to go back to the same</p> <p>23 page we were on, so 122S.</p> <p>24 Go on a little further down from where</p> <p>25 we were with our asbestos discussion.</p>	<p>1 Did I read that correctly?</p> <p>2 A Yes.</p> <p>3 Q "However, the panel agreed that there is</p> <p>4 no known physiological mechanism by which talc can</p> <p>5 plausibly migrate from the perineum to the</p> <p>6 ovaries."</p> <p>7 Did I read that correctly?</p> <p>8 A Yes.</p> <p>9 Q That's exactly what Dr. Belsito was</p> <p>10 saying, right?</p> <p>11 MR. LOCKE: Objection to form.</p> <p>12 THE WITNESS: That -- that's -- he said</p> <p>13 something along those lines, yes.</p> <p>14 BY MR. MEADOWS:</p> <p>15 Q Yeah. He said, you know, we need to</p> <p>16 look at all these other epidemiologic studies, but</p> <p>17 at the end of the day, talc can't get there;</p> <p>18 therefore you can't have causation, therefore it's</p> <p>19 safe, right?</p> <p>20 MR. LOCKE: Objection to form.</p> <p>21 THE WITNESS: That's -- he certainly</p> <p>22 was -- did not believe it could migrate, yes.</p> <p>23 BY MR. MEADOWS:</p> <p>24 Q Yeah. And that ended up in the final</p> <p>25 report, correct?</p>
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<p>1 You'll see the next paragraph starts:</p> <p>2 "As evidenced in this safety assessment." You see</p> <p>3 that?</p> <p>4 A No.</p> <p>5 Q I'm on page 122S. It's -- it's further</p> <p>6 back than that, Doctor. There you go.</p> <p>7 A Okay.</p> <p>8 Q Okay. And if you look at the top</p> <p>9 right-hand corner, we were there a few minutes</p> <p>10 ago. And you'll see the first full paragraph</p> <p>11 starts "As evidenced in this safety assessment."</p> <p>12 A Okay.</p> <p>13 Q All right. So starting with that</p> <p>14 paragraph: "As evidenced in this safety</p> <p>15 assessment, numerous studies have been performed</p> <p>16 to investigate whether or not a causative</p> <p>17 relationship exists between the cosmetic use of</p> <p>18 talc in the perineal area and ovarian cancer. A</p> <p>19 panel reviewed these studies thoroughly and</p> <p>20 determined that they do not support a causal link.</p> <p>21 The panel stated that causation would depend on</p> <p>22 the migration of talc from the perineum to the</p> <p>23 ovaries. There is no conclusive explanation for</p> <p>24 the presence of talc in the ovaries reported in</p> <p>25 some studies."</p>	<p>1 A Yes.</p> <p>2 MR. LOCKE: Objection to form.</p> <p>3 BY MR. MEADOWS:</p> <p>4 Q And that ended up being the basis by</p> <p>5 which this report says the panel determined that</p> <p>6 talc is safe.</p> <p>7 A I think --</p> <p>8 MR. LOCKE: Objection to form.</p> <p>9 THE WITNESS: I think this discussion</p> <p>10 doesn't capture -- I know they also talked about</p> <p>11 the -- the weaknesses in the epidemiology study,</p> <p>12 and with the small -- small relative ratios and</p> <p>13 the -- I mean, there's a big discussion of the --</p> <p>14 if you go back a few pages, of what the different</p> <p>15 case studies found and what the relative risks</p> <p>16 were and what some of the issues were around</p> <p>17 those.</p> <p>18 So it -- I think that should have been</p> <p>19 captured in the discussion, and I --</p> <p>20 BY MR. MEADOWS:</p> <p>21 Q I think they captured it --</p> <p>22 A -- it was not well captured.</p> <p>23 Q I think they captured it in that one</p> <p>24 paragraph in the very first sentence: "As</p> <p>25 evidenced in this safety assessment, numerous</p>

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<p>1 studies have been performed to investigate whether</p> <p>2 or not a causative relationship exists between the</p> <p>3 cosmetic use of talc in the perineal area and</p> <p>4 ovarian cancer."</p> <p>5 In one sentence, they gave a wink and a</p> <p>6 nod to all epidemiology and toxicology information</p> <p>7 that they just cited to in the preceding papers,</p> <p>8 right?</p> <p>9 A No.</p> <p>10 MR. LOCKE: Objection to form,</p> <p>11 mischaracterizes testimony and document.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q Then they went on to say: "The panel</p> <p>14 reviewed these studies thoroughly and determined</p> <p>15 they do not support a causal link. The panel</p> <p>16 stated that causation would depend" -- regardless</p> <p>17 of what they say, I don't care how high the risk</p> <p>18 is -- "it would depend on the migration of talc</p> <p>19 from the perineum to the ovaries. There is no</p> <p>20 conclusive explanation for the presence of talc in</p> <p>21 the ovaries reported in some studies. However,</p> <p>22 the panel agreed there is no known physiological</p> <p>23 mechanism by which talc can plausibly migrate to</p> <p>24 the perineum -- from the perineum to the ovaries."</p> <p>25 It's that simple, isn't it?</p>	<p>1 FDA would be a reputable source of information in</p> <p>2 that regard?</p> <p>3 MR. LOCKE: Same objection.</p> <p>4 BY MR. MEADOWS:</p> <p>5 Q It's a simple "yes" or "no."</p> <p>6 A There's no reference to their statement,</p> <p>7 which is very unusual. It doesn't fit, and I --</p> <p>8 reading it, I truly wondered what the references</p> <p>9 they were using.</p> <p>10 (Exhibit No. 112 was marked for</p> <p>11 identification.</p> <p>12 BY MR. MEADOWS:</p> <p>13 Q And you're referring to what I've marked</p> <p>14 as Exhibit 112, right?</p> <p>15 MR. LOCKE: I don't think we have 112.</p> <p>16 MR. MEADOWS: It's being handed to you.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Okay. You've seen that before, right?</p> <p>19 A I have.</p> <p>20 Q Okay. This is a letter from the FDA to</p> <p>21 Sam Epstein, correct?</p> <p>22 A Yes.</p> <p>23 Q And it is commonly called -- and it's</p> <p>24 dated April 1, 2014, from the FDA to Sam Epstein.</p> <p>25 He filed a -- a petition. I think we talked about</p>
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<p>1 MR. LOCKE: Objection to form,</p> <p>2 mischaracterizes the document and misquotes the</p> <p>3 document.</p> <p>4 THE WITNESS: I think the document goes</p> <p>5 into much more detail about the questions raised</p> <p>6 in the epidemiology studies. I think that should</p> <p>7 have been captured in the discussion, and I would</p> <p>8 agree with you that it is not.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q Now, we both know there's a lot of</p> <p>11 science out there that supports the idea that</p> <p>12 particulate can migrate to the ovaries, right?</p> <p>13 MR. LOCKE: Objection to form.</p> <p>14 THE WITNESS: No. I mean, I -- not the</p> <p>15 way you just worded it. I think there's a lot of</p> <p>16 questions out there.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q Well, would you say the FDA believes --</p> <p>19 do you believe the FDA would be a reputable source</p> <p>20 of information in that regard?</p> <p>21 A I know what you're referring to.</p> <p>22 MR. LOCKE: Objection to form and beyond</p> <p>23 the scope.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q And my question is, do you believe the</p>	<p>1 that in the course of your deposition, right?</p> <p>2 A Yes.</p> <p>3 Q Asking that certain warnings be put on</p> <p>4 baby powder and other body powders, correct?</p> <p>5 A Correct.</p> <p>6 Q And that was filed in -- well, initially</p> <p>7 in 1994, right?</p> <p>8 A That's a different petition. I think</p> <p>9 this was the petition filed in 2008.</p> <p>10 Q "Dear Dr. Epstein: This letter is in</p> <p>11 response to your two Citizen's Petitions dated</p> <p>12 December 17, 1994, and May 13, 2008."</p> <p>13 Did I read that correctly?</p> <p>14 A You did.</p> <p>15 Q Okay. And he asks for certain warnings,</p> <p>16 and the FDA rejected his request, right?</p> <p>17 A Correct.</p> <p>18 Q But in the course of their letter in</p> <p>19 rejecting his request, they speak to this very</p> <p>20 issue of migration, don't they?</p> <p>21 A They do.</p> <p>22 Q And they say: "While there exists no</p> <p>23 direct proof of talc and ovarian carcinogenesis,</p> <p>24 the potential for particulates to migrate from the</p> <p>25 perineum and vagina to the peritoneal cavity is</p>

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<p>1 indisputable."</p> <p>2 Did I read that correctly?</p> <p>3 A I don't know where you are.</p> <p>4 Q I'm sorry. It's on page 5 of 7.</p> <p>5 If you go down a little more than</p> <p>6 halfway, the paragraph starting "While there</p> <p>7 exists." Do you see that?</p> <p>8 A Yes.</p> <p>9 Q Okay. "While there exists no direct</p> <p>10 proof of talc and ovarian carcinogenesis, the</p> <p>11 potential for particulates to migrate from the</p> <p>12 perineum and vagina to the peritoneal cavity is</p> <p>13 indisputable."</p> <p>14 Did I read that correctly?</p> <p>15 A You did read it correctly. I didn't</p> <p>16 know what --</p> <p>17 Q "It is therefore plausible that perineal</p> <p>18 talc and other particulate that reaches the</p> <p>19 endometrial cavity, fallopian tubes, ovaries and</p> <p>20 peritoneum may elicit a foreign body type</p> <p>21 reaction, an inflammatory response that in some --</p> <p>22 that in some exposed women may progress to</p> <p>23 epithelial cancers. However, there has been no</p> <p>24 conclusive evidence to support causality."</p> <p>25 Did I read that correctly?</p>	<p>1 couple of years now, I would assume?</p> <p>2 A I don't know.</p> <p>3 Q PCPC has been, right?</p> <p>4 A Yes.</p> <p>5 Q And we talked a while back when we were</p> <p>6 looking at the procedures, that there's a way for</p> <p>7 the CIR to take up an issue again and look at it.</p> <p>8 Right?</p> <p>9 A Yes.</p> <p>10 Q And there was -- there's a provision in</p> <p>11 the procedures that we talked about that -- that</p> <p>12 says that if at any point in time an issue needs</p> <p>13 to be taken up again, that there's -- the CIR can</p> <p>14 do that, right?</p> <p>15 A That's true.</p> <p>16 Q So in the, what, almost -- well, over</p> <p>17 four years now since this came out from the FDA,</p> <p>18 has the CIR rereviewed and reevaluated their</p> <p>19 position on migration and the safety of talc?</p> <p>20 A No.</p> <p>21 MR. MEADOWS: Okay. That's all I have</p> <p>22 right now. Let me consult with my colleagues, and</p> <p>23 I may be ready to pass. Let me see.</p> <p>24 THE VIDEOGRAPHER: The time is 3:56 p.m.</p> <p>25 We're going off the record.</p>
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<p>1 A You read it correctly, yes.</p> <p>2 Q And that -- that's completely different</p> <p>3 from what the CIR is saying about migration, isn't</p> <p>4 it?</p> <p>5 MR. LOCKE: Objection to form.</p> <p>6 THE WITNESS: No, they are concluding</p> <p>7 the warning is needed, but, yes, it is different.</p> <p>8 MR. MEADOWS: Well, move to strike.</p> <p>9 BY MR. MEADOWS:</p> <p>10 Q My question is simply that the FDA --</p> <p>11 MR. LOCKE: I oppose the motion to</p> <p>12 strike.</p> <p>13 MR. MEADOWS: Sorry, sir?</p> <p>14 MR. LOCKE: I opposed it, your motion to</p> <p>15 strike.</p> <p>16 MR. MEADOWS: Okay. So I'll try again.</p> <p>17 BY MR. MEADOWS:</p> <p>18 Q The FDA in the paragraph that we just</p> <p>19 read specifically says just the opposite of what</p> <p>20 the CIR says about migration, don't they?</p> <p>21 MR. LOCKE: Objection to form.</p> <p>22 THE WITNESS: They reach a different</p> <p>23 conclusion, yes.</p> <p>24 BY MR. MEADOWS:</p> <p>25 Q CIR has been aware of this letter for a</p>	<p>1 (Recess.)</p> <p>2 THE VIDEOGRAPHER: The time is</p> <p>3 4:10 p m., and we're back on the record.</p> <p>4 RECROSS-EXAMINATION</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Dr. Loretz, we're winding down here, so</p> <p>7 I just want to ask you some questions.</p> <p>8 There was a subject 13 on foreign</p> <p>9 regulatory bodies. Are you familiar with that, in</p> <p>10 the notice of deposition?</p> <p>11 A Yes.</p> <p>12 Q And did -- did you review documents to</p> <p>13 help prepare you about the communications between</p> <p>14 any foreign regulatory bodies and the PCPC as it</p> <p>15 relates to the issue of talc and the association</p> <p>16 with ovarian cancer?</p> <p>17 A I'm not sure what -- which bodies you're</p> <p>18 referring to.</p> <p>19 Q Any foreign regulatory body.</p> <p>20 A I'm not sure.</p> <p>21 Q Let me just read for you the -- from the</p> <p>22 notice of deposition.</p> <p>23 It says: "Foreign regulatory bodies,</p> <p>24 communication between you and any foreign nations</p> <p>25 and/or foreign regulatory bodies including, but</p>

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<p>1 not limited to, China, Korea, Canada, the United 2 Kingdom, Germany, or any foreign industry 3 associations including, but not limited to, 4 CTPA" -- that's the Canadian equivalent? 5 A C -- 6 Q CTPA? 7 A -- TPA would be the U.K. 8 Q U.K. EUROTALC. 9 A Okay. 10 Q -- "and IMA Europe concerning talc, J&J 11 defendants, talcum powder products, the science 12 related to the relationship between talcum powder 13 products and ovarian cancer, the composition of 14 talc and any regulations regarding talcum powder 15 products." 16 A Okay. 17 Q Are you prepared to discuss that? 18 A Yes. 19 Q And did you review documents to help you 20 prepare? 21 A Some documents, yes. 22 Q Okay. What -- tell me just generally 23 what type of documents you -- you reviewed. 24 MR. LOCKE: Well, I'm going to object to 25 the extent you're seeking work product. If you</p>	<p>1 China? 2 A Yes, there was work that was done 3 related to the specification for -- or, rather, 4 for -- China had -- had found asbestos or 5 reportedly found asbestos in products, and there 6 was work done, I think led by Dr. John Bailey 7 because he was a chemist, working to try to -- on 8 their analytical methodology. 9 Q And just to be clear, the -- what 10 Chinese regulatory agency are we talking about? 11 A I think it was SFDA, I think. 12 Q And this -- this foreign -- this Chinese 13 regulatory agency found asbestos in the talc? 14 A I think they reported finding, and we -- 15 we were aware, and we're working with a group of 16 industry people, members obviously, CTFA or PCPC, 17 that they reported finding it. We knew, I guess, 18 that the methodology they were using, they were 19 doing x-ray defraction, which is what our 20 methodology is, but they were not following up, as 21 is needed, with microscopy, and so therefore they 22 would find it and call it asbestos when in fact it 23 may well not have been. 24 And I think this is part of a bigger 25 issue of the question of trade barriers and et</p>
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<p>1 want to show her a document and ask her if she 2 reviewed it, that's fine. 3 BY MR. GOLOMB: 4 Q Well, I wasn't asking for any specific 5 document. That's why I specifically said what 6 type of documents. 7 A I mean, I reviewed -- for example, 8 EUROTALC, I think the only thing we ever had 9 communication was during IARC. So those would be 10 e-mails. 11 Q Okay. Was there any communication on 12 EUROTALC with respect to the NTP? 13 A I don't think so. 14 Q Was there any documents with EUROTALC 15 with respect to the CIR report? 16 A I just saw there was a submission. I'm 17 trying to remember if that was IMA Europe or 18 EUROTALC. It was one or the other. But it 19 wouldn't have been -- I think -- I don't think 20 that went through us, so I think -- I think the 21 answer is no. 22 Q Okay. And did the -- did the PCPC as 23 the -- we're talking about the NTP, the IARC, the 24 CIR report, was there any communication between 25 the PCPC and any foreign regulatory bodies in</p>	<p>1 cetera, but -- but the piece related to talc had 2 to do with them reporting the finding of asbestos, 3 and then PCPC with its members working on the 4 issue of methodology. 5 Q And when you say "microscopy," what type 6 of microscopy are you talking about? 7 A Well, the -- the CTFA/PCPC 8 specificate -- or, excuse me, methodology, the J41 9 method uses optical microscopy with -- with 10 staining. 11 Q What about scanning electron microscopy? 12 A I mean, I know that's used by some of 13 our members. It's -- it's not what CTFA spec- -- 14 methodology uses. 15 Q Well, what was -- what is the time 16 period that we're talking about when -- when there 17 was communications between PCPC and China when 18 they found asbestos in the talc? 19 A When they -- 20 MR. LOCKE: Objection to form. 21 THE WITNESS: When they claim they found 22 asbestos in talc, and -- and we were saying making 23 sure they had the correct methodology. 24 BY MR. GOLOMB: 25 Q But my question was what -- what time</p>

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<p>1 period?</p> <p>2 A Right, I'm coming back to that. I just</p> <p>3 wanted to clarify that's what I'm answering. It</p> <p>4 would have been when John Bailey was there, and I</p> <p>5 want to say 2010-ish.</p> <p>6 Q And what was the -- what was the first</p> <p>7 communication between -- was it from -- from the</p> <p>8 Chinese regulatory agency to Mr. Bailey or</p> <p>9 Dr. Bailey?</p> <p>10 A I -- I don't know. I think the problem</p> <p>11 was our members were reporting that the Chinese</p> <p>12 were looking at products that they were importing</p> <p>13 and saying they were finding asbestos. Our</p> <p>14 companies did not believe that to be the case at</p> <p>15 all. These are products manufactured in the U.S.</p> <p>16 that were certainly believed to be asbestos-free,</p> <p>17 and so the concern was in looking at the</p> <p>18 methodology the Chinese were using that they could</p> <p>19 identify asbestos, when, in fact, it was -- it was</p> <p>20 not, and so it was working with them to try to get</p> <p>21 them to use a methodology that would correctly</p> <p>22 identify asbestos.</p> <p>23 Q Okay. So, first of all, which members</p> <p>24 are you talking about that were receiving these</p> <p>25 notices?</p>	<p>1 Q Right.</p> <p>2 A And when I mentioned that J&J was one,</p> <p>3 there were other companies without question.</p> <p>4 Q Okay.</p> <p>5 A But I don't know quite how the</p> <p>6 notification went. I'm certainly a person that</p> <p>7 wasn't involved in that, but I think it was more</p> <p>8 our companies were having products getting their</p> <p>9 products into China for reasons that they did not</p> <p>10 consider to be real, and then they were working</p> <p>11 through PCPC to see if we could get that fixed.</p> <p>12 Q And when -- when PCPC then contacted</p> <p>13 China to -- for lack of a better word, to advise</p> <p>14 them what your standards were, what did they do?</p> <p>15 A There was a whole -- I know there was a,</p> <p>16 I think, a meeting over in China with -- we -- we</p> <p>17 wrote to them. They had a -- they had a</p> <p>18 methodology, and we -- I know -- "we," PCPC --</p> <p>19 with our members, obviously, we input in great</p> <p>20 detail into that methodology with comments on how</p> <p>21 we thought it would be correct so that they would</p> <p>22 in fact not detect asbestos unless it was really</p> <p>23 there.</p> <p>24 Q Okay. And when did this meeting take</p> <p>25 place?</p>
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<p>1 A I -- I don't know. I know that J&J was</p> <p>2 one of them, but there were others as well.</p> <p>3 Q Was Imerys one of them?</p> <p>4 A No, because they don't make product. So</p> <p>5 that wouldn't -- this was again on imported</p> <p>6 products, products imported to China.</p> <p>7 Q Okay. Product imported from the United</p> <p>8 States to China?</p> <p>9 A Correct. Which is why part of the</p> <p>10 reason we believed that -- I mean, that this was</p> <p>11 something to do with trade barriers as well.</p> <p>12 Q Right. And once -- once these -- the</p> <p>13 Chinese agencies received the talc from J&J or</p> <p>14 some other member, PCPC member perhaps, that's</p> <p>15 when the Chinese groups did their own testing,</p> <p>16 found asbestos in the talc, and then somehow</p> <p>17 notified PCPC?</p> <p>18 MR. LOCKE: Objection to form.</p> <p>19 MS. FRAZIER: Object to form.</p> <p>20 THE WITNESS: No. I -- I don't believe</p> <p>21 so. So this was not talc like talcum powder. I</p> <p>22 mean, it could have been that as well, but I'm</p> <p>23 talking about like products like eye shadows and</p> <p>24 talc-containing products.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 A I -- I don't know. I'm sorry. I just</p> <p>2 can't keep all my years straight. It was in that</p> <p>3 kind of 2010 -- it was when John Bailey was there.</p> <p>4 So that would have been -- put it around, yeah,</p> <p>5 probably 2010 on the outside, 2009. I'm not sure.</p> <p>6 Q Who attended the meeting?</p> <p>7 A The meeting in China, I don't know.</p> <p>8 Q Who from PCPC attended?</p> <p>9 A I'm not sure anybody from PCPC attended,</p> <p>10 but I know that we were involved with commenting</p> <p>11 on the specification.</p> <p>12 Q Did any -- did anybody from J&J go?</p> <p>13 A I -- yes, I think someone from J&J did</p> <p>14 go.</p> <p>15 Q Who from J&J went?</p> <p>16 A I think a woman named Jane Cai, C-A-I.</p> <p>17 Q Jane?</p> <p>18 A Yes, I think it's C-A-I. I think she's</p> <p>19 Chinese, and I assume that had perhaps something</p> <p>20 to do with the fact that she would be one who</p> <p>21 would go.</p> <p>22 Q And who was it from -- do you know</p> <p>23 who -- not necessarily the individuals, but the</p> <p>24 companies that were represented in China?</p> <p>25 A I wish -- I wish I could tell you. I</p>

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<p>1 don't know. There -- as I say, there were others.</p> <p>2 And I should also say that the</p> <p>3 correspondence from PCPC that went to China was</p> <p>4 from Francine Lamoriello, which I just mentioned</p> <p>5 that's our international department, because this</p> <p>6 was an international issue.</p> <p>7 Q And is that a -- Francine Lamoriello, is</p> <p>8 that a PCPC employee?</p> <p>9 A Yes.</p> <p>10 Q And what is her title?</p> <p>11 A She's the executive VP of inter- -- of</p> <p>12 our international department.</p> <p>13 Q And what was -- what was done to --</p> <p>14 well, strike that.</p> <p>15 So once -- are you familiar with JPB in</p> <p>16 China?</p> <p>17 A No.</p> <p>18 Q Once the -- you received notification</p> <p>19 from China that they were finding asbestos in the</p> <p>20 talc, what was done -- other than sending a letter</p> <p>21 -- how did -- how did PCPC learn of what</p> <p>22 specifications the Chinese were using?</p> <p>23 A I think -- I mean, I don't know how it</p> <p>24 went through, but I -- I know that that became --</p> <p>25 I mean, that was something the Chinese had to</p>	<p>1 issue, what do you mean by that?</p> <p>2 A I think there were other trade issues,</p> <p>3 and again, this was -- this was the Chinese</p> <p>4 supposedly finding asbestos in products coming</p> <p>5 from the U.S. products going to China, where our</p> <p>6 members were very comfortable that in fact they</p> <p>7 did not contain that. And I think this was one of</p> <p>8 several issues where the -- you know, the Chinese</p> <p>9 were promoting their own Chinese products,</p> <p>10 rejecting products that were coming in.</p> <p>11 Q So you think that the Chinese were --</p> <p>12 were creating the asbestos issue?</p> <p>13 A I think that they weren't testing them</p> <p>14 using the proper methodology, and that created an</p> <p>15 issue.</p> <p>16 Q Okay. And -- and so what was the time</p> <p>17 period between when the Chinese started to reject</p> <p>18 the -- what they said was the talc with asbestos</p> <p>19 in it until this meeting took place?</p> <p>20 MR. LOCKE: Objection to form.</p> <p>21 THE WITNESS: I'm -- I'm not sure. And</p> <p>22 again, I just say it's talc -- products with talc,</p> <p>23 not -- and that was another problem that I think</p> <p>24 there was -- you know, they were testing.</p> <p>25 BY MR. GOLOMB:</p>
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<p>1 provide, and the Chinese were working on their --</p> <p>2 their specification, again their methodology</p> <p>3 that -- supporting that specification. And so</p> <p>4 they were working with us, because I know that we</p> <p>5 had their spec- -- their methodology, and again</p> <p>6 were commenting on it in -- in great detail.</p> <p>7 Q So were there communications with --</p> <p>8 with the Chinese about this before they notified</p> <p>9 PCPC about finding talc -- asbestos in the talc?</p> <p>10 MR. LOCKE: Objection to form.</p> <p>11 THE WITNESS: Yeah, I don't know that</p> <p>12 they ever notified us. As I say, I think they</p> <p>13 notified our members because they were rejecting</p> <p>14 their product, and then -- and then probably our</p> <p>15 members came to us. That would be the way I</p> <p>16 expect it went.</p> <p>17 No, this was -- this was how I think the</p> <p>18 issue got brought up is our members were having</p> <p>19 this problem, again, believed to be a trade issue,</p> <p>20 because we don't think those products ever had</p> <p>21 asbestos in it.</p> <p>22 But that's how it came up and that's how</p> <p>23 we ended up working with them.</p> <p>24 BY MR. GOLOMB:</p> <p>25 Q Well, when you said that it's a trade</p>	<p>1 Q Are we talking about a period of weeks,</p> <p>2 months, years?</p> <p>3 A I would say -- I'm going to guess and</p> <p>4 say months.</p> <p>5 Q Okay. And during this months long</p> <p>6 period of time, while the -- from the time of the</p> <p>7 notice of the -- of asbestos in the talc until the</p> <p>8 time of the meeting, did the Chinese continue to</p> <p>9 reject the talc?</p> <p>10 MR. LOCKE: Objection to form.</p> <p>11 THE WITNESS: I can say that I'm sure</p> <p>12 it -- I'm pretty sure it continued to be an issue,</p> <p>13 but I don't know whether it was people stopped</p> <p>14 sending it or they were still rejecting, I really</p> <p>15 don't know.</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q And so --</p> <p>18 A It was still an issue, though.</p> <p>19 Q So what were the -- what was the purpose</p> <p>20 of the meeting?</p> <p>21 A I'm -- the purpose was again to inform</p> <p>22 them of methodology that was better than what they</p> <p>23 was using -- they were using. Again, they were --</p> <p>24 I mean, they were revising their methodology, so</p> <p>25 they welcomed, I think, our input or said they</p>

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<p>1 did.</p> <p>2 So it was to present on -- on</p> <p>3 methodology and -- it was to present on</p> <p>4 methodology, I believe.</p> <p>5 Q Okay. So what happened as a result of</p> <p>6 the meeting?</p> <p>7 A My understanding is I think the issue</p> <p>8 went away, so I -- and I know they were revising</p> <p>9 their methodology, so I assume they came up with a</p> <p>10 final methodology that --</p> <p>11 Q And when was that?</p> <p>12 A I -- that I couldn't tell you. I mean,</p> <p>13 in the same time frame, I think.</p> <p>14 Q Okay. And --</p> <p>15 A I'm not sure.</p> <p>16 Q And have there been any similar issues</p> <p>17 with the Chinese since then?</p> <p>18 A Not that I'm aware of.</p> <p>19 Q Okay. When you say not that you're</p> <p>20 aware of, have you reviewed documents that</p> <p>21 indicate one way or another as to whether or not</p> <p>22 there is a continuing problem with the Chinese and</p> <p>23 asbestos in the talc?</p> <p>24 A I have seen no documents and that's --</p> <p>25 and nor heard of anything. That's what makes me</p>	<p>1 A It will come to me.</p> <p>2 Q Okay. And how often are there</p> <p>3 communications with this Chinese trade</p> <p>4 association?</p> <p>5 A On issues -- any issues?</p> <p>6 Q Yeah, issues related to talc.</p> <p>7 A Oh, issues related to talc. I'm not --</p> <p>8 I'm not aware other than that one period of time.</p> <p>9 Q Okay. Same question for Korea, is there</p> <p>10 a -- is there a trade association related to talc</p> <p>11 in Korea?</p> <p>12 A And again, just to go back, the Chinese</p> <p>13 trade association I'm talking about is not a talc</p> <p>14 trade association. It's an industry, like -- it's</p> <p>15 like equivalent to PCPC in China.</p> <p>16 Q Okay. So just to be clear, that -- the</p> <p>17 trade organization that you're talking about in</p> <p>18 China is something of a counterpart to PCPC in</p> <p>19 China?</p> <p>20 A Yes.</p> <p>21 Q EUROTALC obviously is a trade</p> <p>22 association specifically related to talc?</p> <p>23 A Correct.</p> <p>24 Q Are you -- are you aware of any other</p> <p>25 foreign bodies that are -- that are trade</p>
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<p>1 say I don't think it's still a continuing issue.</p> <p>2 Q Okay. And before this issue arose, how,</p> <p>3 if at all, did -- how, if at all, did the PCPC</p> <p>4 communicate with the foreign regulatory bodies</p> <p>5 in -- in China?</p> <p>6 A On issues related to talc?</p> <p>7 Q Yeah.</p> <p>8 A I guess I'm not aware of communications</p> <p>9 or problems or anything.</p> <p>10 Q Okay. Is there -- but we talked a</p> <p>11 little bit about EUROTALC, and EUROTALC is what?</p> <p>12 A It's a trade association specific for</p> <p>13 talc in Europe.</p> <p>14 Q Okay. Is there any similar agency in</p> <p>15 China?</p> <p>16 A I guess not that I'm aware of. I</p> <p>17 think -- I think who we usually work with there --</p> <p>18 I mean, there is a trade association, and I think</p> <p>19 they were probably involved in that. And part of</p> <p>20 the reason I say that is, is that when we deal</p> <p>21 with the Chinese authority on various issues, and</p> <p>22 that's an ongoing thing, we do work with the</p> <p>23 Chinese trade association.</p> <p>24 Q And that's -- what's the name of the</p> <p>25 Chinese trade association?</p>	<p>1 associations specifically related to talc?</p> <p>2 A I guess I would say I'm not.</p> <p>3 Q Okay. Now, with respect to -- we</p> <p>4 started to talk about Korea. Are there -- are</p> <p>5 there communications between PCPC or any of its</p> <p>6 members that you know about as it relates to the</p> <p>7 business of talc in Korea?</p> <p>8 A You know, not that I know about. I</p> <p>9 mean, I know I saw reference to that from the --</p> <p>10 at the meeting that took place with the FDA that</p> <p>11 there is a Korean issue, but I -- I did not review</p> <p>12 any documents and I didn't hear anything about it,</p> <p>13 so I'm not aware.</p> <p>14 Q All right. When you say "Korea issue,"</p> <p>15 what are you referring to?</p> <p>16 A Just that we -- I looked at documents --</p> <p>17 we looked at a document yesterday where the</p> <p>18 meeting that PCPC and some of its members had with</p> <p>19 FDA in -- I think it was 2009, there was a</p> <p>20 reference to there being an issue with Korea.</p> <p>21 Q What was the Korea issue?</p> <p>22 A I don't know. You're asking about</p> <p>23 Korea, and that's -- there was some sort of issue</p> <p>24 related to talc, and I don't know what it was.</p> <p>25 Q Okay. We -- we talked at various</p>

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<p>1 times -- you talked to me about it, you talked to</p> <p>2 Mr. Tisi about it yesterday -- about the federal</p> <p>3 regulation in the United States, the establishment</p> <p>4 of warnings.</p> <p>5 A Yes.</p> <p>6 Q Do you recall that?</p> <p>7 And which says under 740.1: "The</p> <p>8 Establishment of Warning Statements. (a) the</p> <p>9 label of a cosmetic product shall bear a warning</p> <p>10 statement whenever necessary or appropriate to</p> <p>11 prevent a health hazard that may be associated</p> <p>12 with the product."</p> <p>13 Do you recall the questions about that?</p> <p>14 A Yes.</p> <p>15 Q All right. Are you familiar with any</p> <p>16 similar kinds of regulations, whether it's in</p> <p>17 China, Korea, Canada, the U.K., Germany or Europe</p> <p>18 generally?</p> <p>19 A I am not.</p> <p>20 Q Are -- so are you -- are you aware</p> <p>21 generally of the -- the regulation placed upon the</p> <p>22 cosmetic industry in these various countries?</p> <p>23 MR. LOCKE: Objection to form.</p> <p>24 THE WITNESS: No, not really.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 A It's called quasi-drug, and I -- yeah.</p> <p>2 Q Okay. And meaning what?</p> <p>3 A I'm not sure. I -- I -- yeah.</p> <p>4 Q Okay. Do they -- do they -- as an</p> <p>5 example, like in pharmaceuticals here in the</p> <p>6 United States, do they have a preapproval process</p> <p>7 for cosmetics?</p> <p>8 MR. LOCKE: Objection to form and beyond</p> <p>9 the scope.</p> <p>10 THE WITNESS: I'm not sure. I -- I want</p> <p>11 to say I don't think so, but I'm not sure.</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Okay. I had asked you before about a --</p> <p>14 we were talking about a time frame, and I asked</p> <p>15 you about the NTP time frame before.</p> <p>16 A Okay.</p> <p>17 MR. GOLOMB: Could we have -- I don't</p> <p>18 know, Exhibit 22.</p> <p>19 (Counsel conferring.)</p> <p>20 (Exhibit No. 113 was marked for</p> <p>21 identification.)</p> <p>22 BY MR. GOLOMB:</p> <p>23 Q Now, this is a PCPC document which has</p> <p>24 been Bates-stamped 55865. We've marked it for</p> <p>25 identification as 113.</p>
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<p>1 Q Are you aware one way or the other as to</p> <p>2 whether or not they have stricter regulations,</p> <p>3 more liberal regulations, or roughly the same?</p> <p>4 MR. LOCKE: Objection to form and beyond</p> <p>5 the scope.</p> <p>6 THE WITNESS: Related to talc?</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q Related to cosmetics.</p> <p>9 A I mean, there's -- there's differences.</p> <p>10 I'm aware of some differences, but --</p> <p>11 Q Like -- like what, as an example?</p> <p>12 A Well, I mean, for example, if you want</p> <p>13 to go to Europe, you can -- some specific</p> <p>14 ingredients might have differences. The way</p> <p>15 they -- sunscreens are drugs in the U.S., and in</p> <p>16 Europe they're cosmetics. They may have some</p> <p>17 limits on ingredients that aren't the same as</p> <p>18 ours. So there's -- there's a whole -- I mean,</p> <p>19 there's a myriad.</p> <p>20 Same with Japan, they have a -- they</p> <p>21 have a quasi-drug regulation. So, I mean, there's</p> <p>22 lots of differences, sure.</p> <p>23 Q When you -- when you say in Japan, we're</p> <p>24 talking specifically they have a quasi-drug --</p> <p>25 what was the word you used?</p>	<p>1 Have you seen this document before?</p> <p>2 A No.</p> <p>3 Q Why don't you -- if you -- if you look</p> <p>4 at page 3 of the document, it refers to talc.</p> <p>5 Take a look at that.</p> <p>6 MR. LOCKE: Just for the record, the</p> <p>7 exhibit, it's page 2, and we're talking about</p> <p>8 Bates numbers 867. The first page was 865.</p> <p>9 Probably not an issue, but just clarifying.</p> <p>10 MR. GOLOMB: Right. 865 is the cover</p> <p>11 page of the document, and 867 is where the</p> <p>12 discussion about talc begins.</p> <p>13 THE WITNESS: (Peruses document.)</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Okay. Have you seen that document</p> <p>16 before?</p> <p>17 A No.</p> <p>18 Q Do you know generally what this document</p> <p>19 is?</p> <p>20 A I just know it says "Executive Committee</p> <p>21 Meeting."</p> <p>22 Q And what is -- what is a document like</p> <p>23 this that says "Executive Committee Meeting"</p> <p>24 generally?</p> <p>25 A Well, executive committee is a -- is a</p>

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<p>1 top -- high level from our member companies that 2 meets maybe four times a year. 3 Q And these are PCPC high level exec -- 4 executives of PCPC members that meet with who? 5 A That meet with PCPC staff. But I 6 don't -- like I really don't know who wrote this. 7 Q Okay. But you've seen minutes like -- 8 meeting minutes like this before. 9 A Actually, I haven't, just because I 10 don't go to executive committee meetings, but I -- 11 I mean, that's what I assume it is. 12 Q And in your role with PCPC, you don't 13 have access to minutes like -- meeting minutes 14 like this? 15 A Not for the executive committee, no. 16 Q Okay. Who from PCPC would attend an 17 executive committee meeting like this? 18 A Higher -- the senior staff. I mean, 19 Lezlee Westine, our CEO. Mark Pollack -- 20 Q Well, who was the CEO -- I'm sorry. 21 A I'm sorry. 22 Q Who was the CEO back in 2001? 23 A Oh, sorry. That would have been -- so 24 the CEO back in 2001 was still Ed Kavanaugh. 25 Q And when did Ed Kavanaugh leave PCPC?</p>	<p>1 Q But you don't -- when -- is the -- is it 2 an annual membership for everybody? 3 A I believe so. 4 Q Okay. So a membership would go from 5 January 1st of any given year to December 31st? 6 A I think that's right. 7 Q Okay. And if somebody joins midyear, 8 what is the membership rate prorated? 9 A I -- 10 MR. LOCKE: Objection. Beyond the 11 scope. This was within Mr. Pollack's area of 12 expertise. 13 BY MR. GOLOMB: 14 Q Is the membership prorated if somebody 15 comes in midyear? 16 A I don't know, but I would assume so, 17 yes. 18 Q All right. So you have, give or take, 19 600 members at any given time. How is it decided 20 which of the members are -- go to an executive 21 committee meeting like that -- that's reflected in 22 these minutes in January 2001? 23 A I guess the short answer is -- I mean, 24 I -- the executive committee is a standing 25 committee. So, I mean, obviously the members</p>
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<p>1 A I think 2005. 2 Q And did Ed Kavanaugh retire in 2005? 3 A He did. 4 Q And is Ed Kavanaugh still alive, do you 5 know? 6 A Yes. 7 Q Is Ed Kavanaugh related to Brett 8 Kavanaugh? 9 A He's his father. 10 Q Why are -- although you're not -- don't 11 have access to these meeting minutes, do you know 12 why these are created? 13 A The only thing I can say is perhaps all 14 of our meetings -- all our meetings have minutes. 15 I mean, it's kind of standard, so -- 16 Q Well, you have, give or take, 17 approximately 600 members, correct? 18 A Yes. 19 Q By the way, when did Imerys leave as a 20 member? 21 A I believe they left this year. 22 Q Do you know when this year? 23 A I don't, no. I think they didn't rejoin 24 this year, so I think that means they were no 25 longer members in 2018.</p>	<p>1 change with time, but I would have to say I don't 2 know how those decisions are made. 3 Q Okay. So as an example of who -- what 4 members currently sit on the executive committee? 5 A I don't know. 6 Q How many members sit on the executive 7 committee? 8 A I don't know, but I think the number is 9 pretty small. 10 Q What's pretty small? 11 A And the reason I say this is there's the 12 board, and I can roughly know the size of that, 13 not that that's what you're asking. But I believe 14 the executive committee is smaller than that. 15 Q Okay. 16 A So if the board has 35 members -- I'm 17 making up a number, I think it's less than that -- 18 the executive committee might be more like ten, 19 but, again, I'm not claiming to be an expert on 20 this. 21 Q And what is the purpose of an executive 22 committee like this? 23 A Versus the board, I'm actually not sure. 24 Q Okay. And are you familiar with Pharma 25 Tech?</p>

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<p>1 A I am not.</p> <p>2 Q Do you know whether or not Pharma Tech</p> <p>3 is a member of PCPC?</p> <p>4 A No.</p> <p>5 MR. LOCKE: Objection. I believe this</p> <p>6 was asked of Mr. Pollack.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q So let's take a look at the -- the</p> <p>9 document.</p> <p>10 A Okay.</p> <p>11 Q Take a look at Bates-stamped page, the</p> <p>12 last three numbers are 867, where the talc</p> <p>13 discussion begins.</p> <p>14 A Okay.</p> <p>15 Q And let's take a look at the second</p> <p>16 paragraph.</p> <p>17 A Okay.</p> <p>18 Q Now, this is January 25th, 2001,</p> <p>19 correct?</p> <p>20 A Yes.</p> <p>21 Q So this is shortly after the NTP dis- --</p> <p>22 decision?</p> <p>23 A Correct.</p> <p>24 Q And under the second paragraph, it says:</p> <p>25 "CTFA brought together companies, not just CTFA</p>	<p>1 Q Well, what did Colipa do to assist the</p> <p>2 PCPC and its members to succeed in front of the</p> <p>3 NTP?</p> <p>4 A They sponsored --</p> <p>5 MR. LOCKE: Objection to form.</p> <p>6 THE WITNESS: They sponsored a -- one of</p> <p>7 the presentations.</p> <p>8 BY MR. GOLOMB:</p> <p>9 Q Which presentation did they sponsor?</p> <p>10 A I don't remember.</p> <p>11 Q And how is it that you know that?</p> <p>12 A Because I was involved.</p> <p>13 Q Okay. So you remember that Colipa was</p> <p>14 involved in a -- in a talc presentation before the</p> <p>15 NTP, but you don't remember which one?</p> <p>16 A Correct.</p> <p>17 Q Okay. How many different talc</p> <p>18 presentations were there in front of the NTP?</p> <p>19 A I don't remember. There were definitely</p> <p>20 several -- six, seven. Well, there were -- I</p> <p>21 mean, there were ones that had to do with -- from</p> <p>22 the cosmetic industry, there were mineralogists.</p> <p>23 There were others that were outside having nothing</p> <p>24 to do with us.</p> <p>25 Q Okay. And did Colipa, in part, fund or</p>
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<p>1 members, but also outside organizations such as</p> <p>2 Colipa, CCTFA, British Thoracic Society, and</p> <p>3 EUROTALC. We coordinated the responses so that</p> <p>4 there would be a coherent and powerful</p> <p>5 presentation. As you know, we succeeded."</p> <p>6 First of all, the -- what is Colipa?</p> <p>7 A Colipa is the European cosmetic trade</p> <p>8 association. They are now called Cosmetics</p> <p>9 Europe.</p> <p>10 Q Okay. And CCTFA?</p> <p>11 A Is the U.K. -- it's -- I'm sorry. I'm</p> <p>12 sorry. CCTFA is Canada, so that's the -- used to</p> <p>13 be -- their old name was Canadian CTFA.</p> <p>14 Q All right. So what was the -- the</p> <p>15 coordination between the PCPC and these</p> <p>16 foreign agencies to help get this successful</p> <p>17 result in front of the NTP?</p> <p>18 MR. LOCKE: Objection to form.</p> <p>19 THE WITNESS: The coordination was just</p> <p>20 that we needed more time because there were so</p> <p>21 many issues to present. So some of the</p> <p>22 presentations were sponsored by members -- by</p> <p>23 these organizations. I mean, because they also</p> <p>24 had an interest in this topic.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 help fund with the PCPC whatever the presentation</p> <p>2 was in front of the NTP?</p> <p>3 A They -- they did not fund.</p> <p>4 Q Okay. So what was their role?</p> <p>5 A They requested time on the agenda. They</p> <p>6 obviously approved what the -- the content of the</p> <p>7 presentation was.</p> <p>8 The NTP allows five minutes per</p> <p>9 presentation, which is a very, very short time</p> <p>10 given the complex issues, and I recall the two --</p> <p>11 they were looking at mineralogy, they were looking</p> <p>12 at inhalation, they were looking at ovarian</p> <p>13 cancer, and there's an enormous number of studies.</p> <p>14 So in order to have more time, so we</p> <p>15 requested their help. And, again, they were -- I</p> <p>16 mean, they certainly approved the content of -- so</p> <p>17 they requested time on the agenda and were given</p> <p>18 time on the agenda.</p> <p>19 Q Okay. And so were they the ones who</p> <p>20 prepared the presentation?</p> <p>21 A The presentations were prepared by</p> <p>22 the -- I mean, for example, we've talked about</p> <p>23 Pastides -- Dr. Pastides doing a presentation, so</p> <p>24 he -- he prepared the presentation.</p> <p>25 Q Okay. Did -- and did Dr. Pastides, did</p>

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<p>1 he do all the presentations?</p> <p>2 A No. He did one.</p> <p>3 Q Okay.</p> <p>4 A Again, he gets five minutes, that's all.</p> <p>5 Q Right. And -- and so if you -- if you</p> <p>6 had seven separate presentations in front of --</p> <p>7 well, strike that.</p> <p>8 The way to get seven -- seven separate</p> <p>9 presentations in front of the NTP was to have</p> <p>10 seven different speakers?</p> <p>11 MR. LOCKE: Objection to form.</p> <p>12 THE WITNESS: It was to have seven</p> <p>13 organizations requesting time on the agenda.</p> <p>14 BY MR. GOLOMB:</p> <p>15 Q Okay. So if there were more foreign</p> <p>16 agencies that you were dealing with, you could</p> <p>17 have gotten more time?</p> <p>18 MR. LOCKE: Objection to form.</p> <p>19 THE WITNESS: And let me just make</p> <p>20 clear. I -- I can't recall exactly who we</p> <p>21 requested time of, but it wasn't seven. I mean,</p> <p>22 I'm referring -- there were a number of</p> <p>23 presentations that had nothing -- that weren't</p> <p>24 related to us. We perhaps did three.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 more presentation time.</p> <p>2 Q Well, were there other foreign</p> <p>3 associations that may have been contacted but did</p> <p>4 not want to be involved in the NTP presentation?</p> <p>5 A No, there were not.</p> <p>6 Q All right. And what did the CCTFA do to</p> <p>7 help succeed in -- in front of the NTP?</p> <p>8 A If -- if we contacted them -- and I'm</p> <p>9 saying Colipa because I specifically remembered</p> <p>10 that. If CCTFA was contacted, and I can believe</p> <p>11 that happened, then they would have done exactly</p> <p>12 the same thing, to request -- to request time so</p> <p>13 that we would have more time to have one of our</p> <p>14 experts present.</p> <p>15 Q Okay. And do you recall who it was that</p> <p>16 presented the CCTFA portion?</p> <p>17 A Again, it would have been one of our</p> <p>18 experts that prepared a -- a submission.</p> <p>19 Q Okay. And so, just so I'm clear, the --</p> <p>20 the -- let's just take the -- whatever the</p> <p>21 presentation was for the CCTFA, that -- that</p> <p>22 presentation would have been prepared by somebody</p> <p>23 at PCPC?</p> <p>24 A No.</p> <p>25 MR. LOCKE: Objection.</p>
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<p>1 Q Okay. When you say "we," you're talking</p> <p>2 about PCPC?</p> <p>3 A PCPC, yeah.</p> <p>4 Q Okay. Well, were there foreign agencies</p> <p>5 other than Colipa, CCTFA, British Thoracic Society</p> <p>6 and EUROTALC that PCPC contacted but didn't want</p> <p>7 to be involved?</p> <p>8 A No --</p> <p>9 MR. LOCKE: Objection. These are not</p> <p>10 foreign agencies.</p> <p>11 THE WITNESS: So I --</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q Foreign associations.</p> <p>14 A I don't know what the British Thoracic</p> <p>15 Society is, but I can promise you we did not</p> <p>16 contact them, so I'm not -- I think this is just</p> <p>17 an error.</p> <p>18 And EUROTALC, I can't remember, I think</p> <p>19 they probably made a presentation on their own</p> <p>20 behalf. Again, I just can't remember, but that --</p> <p>21 this is not an accurate assessment as written</p> <p>22 here. And I don't know who wrote it, but, I</p> <p>23 mean -- but the concept is -- is -- we perhaps had</p> <p>24 CCTFA. I recall we had Colipa. But, again, it</p> <p>25 was them requesting time so that we would have</p>	<p>1 BY MR. GOLOMB:</p> <p>2 Q I mean, the physical document, was there</p> <p>3 a physical document that was submitted to the NTP?</p> <p>4 A So, I mean, we -- as you know, we had</p> <p>5 experts who prepared physical documents that were</p> <p>6 submitted as part of our comments, and -- and we</p> <p>7 itemized that on a, you know, Here is our -- here</p> <p>8 is our comments to you, NTP, on these various</p> <p>9 issues. And then presentations would have been</p> <p>10 done by those experts, and I'm not recalling who</p> <p>11 exactly presented, but they would have prepared</p> <p>12 their own presentation. Whether they -- whether</p> <p>13 it was -- whether they had slides or whether they</p> <p>14 just spoke, I can't recall.</p> <p>15 Q Okay. And then they just -- so those</p> <p>16 experts prepared in advance, whatever the</p> <p>17 presentation was, they made the presentation in</p> <p>18 front of the NTP, and so what was the CCTFA</p> <p>19 involvement?</p> <p>20 A Again, it would have been the same as</p> <p>21 Colipa, that -- that they could have, and I don't</p> <p>22 recall if they did, but they could have sponsored</p> <p>23 a requested time on the agenda, and then reviewed</p> <p>24 a -- reviewed a submission to make sure they were</p> <p>25 certainly in agreement with them, and these</p>

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<p>1 were -- these were organizations that cared about 2 this issue as well. 3 Q Okay. And what was EUROTALC's 4 involvement in the presentation in front of the 5 NTP? 6 A I don't recall, but I -- I am pretty 7 darn certain that it would have been -- EUROTALC 8 would have been requesting their own time to make 9 their own presentation. 10 Q Okay. So then, although we don't know 11 who the writer is of this, we know that this is a 12 PCPC document, right? 13 A Based on the Bates stamp, yes. 14 Q Right. Which means it would have been 15 produced in this litigation by PCPC. 16 A Yes. 17 Q And so it says: "CTFA brought together 18 companies, not just CTFA members, but also outside 19 organizations such as Colipa, CCTFA, British 20 Thoracic Society and EUROTALC." 21 You don't -- you said you think that the 22 British Thoracic Society was a mistake? 23 A We didn't bring them together. I don't 24 even know who they are. 25 Q Okay. Well -- and -- and you said that</p>	<p>1 Q Okay. Prior to the NTP activity in 2001 2 and early -- I mean, in 2000 and early 2001, you 3 mentioned before a -- the Japanese issue. Was -- 4 was that before or after the NTP? 5 A I'm sorry. I don't know what -- a 6 Japanese issue? Chinese? 7 Q Didn't you mention before a Japanese 8 issue? 9 A No. 10 Q Okay. You mentioned a Korean issue. 11 A I mentioned that there was mention of a 12 Korean issue, and I -- I personally don't know 13 anything about it, so I'm not sure if PCPC got 14 involved at all. 15 Q Okay. So we've talked a little bit 16 about the federal -- well, strike that. 17 Tell me if you agree or disagree with 18 the following statement. That: "The two most 19 important laws pertaining to cosmetics marketing 20 in the United States are the Federal Food, Drug, 21 and Cosmetic Act and the Fair Packaging and 22 Labeling Act." 23 MR. LOCKE: Objection to -- it's beyond 24 the scope. 25 You can answer if you can.</p>
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<p>1 EUROTALC would have done their own presentation. 2 A That would be my assumption. 3 Q Okay. So why is it that the PCPC then 4 is taking credit for bringing these people 5 together? 6 A I -- I don't know who wrote this. 7 Q If you go to the next paragraph, it 8 says: "One company provided exception -- one 9 company provided exceptional report -- support, 10 J&J, and especially Helen Han Hsu worked very 11 closely with CTFA staff and invaluable -- and was 12 invaluable." 13 Do you see that? 14 A Yes. 15 Q All right. And in what way did J&J 16 provide -- first of all, do you agree with that 17 statement? 18 A Yes, I know Helen Han Hsu, and she was 19 involved in -- in all the efforts. 20 Q Okay. And was she involved in any way, 21 as far as you know, with the -- the foreign 22 regulatory associations we've been talking about? 23 A No. J&J had their own presentation. 24 They requested time and had a presentation from 25 Dr. Judith Jones, who was an epidemiologist.</p>	<p>1 THE WITNESS: I -- I'm not sure I'm the 2 right person to answer that. 3 BY MR. GOLOMB: 4 Q Okay. Are you -- are you familiar with 5 the Federal Food and Drug -- and Cosmetic Act? 6 A Yes. 7 Q And are you familiar with the Fair 8 Packaging and Labeling Act? 9 A I'm certainly not an expert on it. 10 I'm -- I'm familiar with it, though, yes. 11 Q And are you at all familiar with similar 12 regulations or laws in any of the foreign 13 countries that we've been talking about? 14 MR. LOCKE: Objection to form and asked 15 and answered. 16 THE WITNESS: For the most part, not -- 17 not terribly familiar, no. 18 BY MR. GOLOMB: 19 Q Okay. When you say "for the most part, 20 not terribly familiar," what do you mean? 21 A Well, for example, I'm fairly familiar 22 with Europe requirements on ingredients in a 23 general sense. So that would be one area that I'm 24 pretty familiar with. But am I familiar with 25 labeling and other requirements in countries, no.</p>

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<p>1 For the most part, no.</p> <p>2 Q Okay. Are you familiar with any of the</p> <p>3 similar laws in either the European Union or in</p> <p>4 the U.K.?</p> <p>5 MR. LOCKE: Objection. Beyond the</p> <p>6 scope.</p> <p>7 THE WITNESS: Again, with ingredients</p> <p>8 I'm fairly familiar. But certainly it's not my</p> <p>9 area of expertise at all. That's why we have an</p> <p>10 international department.</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q Okay. Let me show you the next</p> <p>13 document. We will mark this for identification as</p> <p>14 Exhibit 114.</p> <p>15 (Exhibit No. 114 was marked for</p> <p>16 identification.)</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q And I will represent to you that this is</p> <p>19 a J&J document, Bates-stamped 494340.</p> <p>20 First of all, have you seen that</p> <p>21 document before?</p> <p>22 A No.</p> <p>23 Q Why don't you take a look at it.</p> <p>24 A (Peruses document.)</p> <p>25 Q Let me -- I'll ask you some questions --</p>	<p>1 The EU Cosmetic Directive 96/768/EEC was revised</p> <p>2 in January of 2003 to ban 1100 chemicals from</p> <p>3 cosmetics. The USFDA has banned only nine."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q That -- and then the next paragraph</p> <p>7 says: "That means that companies are no longer</p> <p>8 allowed to sell personal care products in the</p> <p>9 European Union that are made with chemicals that</p> <p>10 are known or suspected to cause cancer."</p> <p>11 Okay?</p> <p>12 A Right. I think they're quoting the</p> <p>13 Campaign for Safe Cosmetics.</p> <p>14 Q I'm sorry?</p> <p>15 A I think they're quoting the Campaign for</p> <p>16 Safe Cosmetics.</p> <p>17 Q Right. And so do you -- do you know one</p> <p>18 way or the other or does PCPC know one way or the</p> <p>19 other as to whether or not the European laws are</p> <p>20 more strict for cosmetics than the -- the American</p> <p>21 laws?</p> <p>22 MR. LOCKE: Objection to form and beyond</p> <p>23 the scope.</p> <p>24 THE WITNESS: This is a very, very</p> <p>25 misleading way to put it. The -- as -- as it</p>
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<p>1 A Sure.</p> <p>2 Q -- and then I'll just direct your</p> <p>3 attention to specific paragraphs.</p> <p>4 A Okay.</p> <p>5 Q It's a -- the document is dated</p> <p>6 January 19, 2009, and it says "Policy Area:</p> <p>7 Cosmetic Regulations." You've never seen this</p> <p>8 document before?</p> <p>9 A No.</p> <p>10 Q Have you seen any -- a document like</p> <p>11 this before from J&J?</p> <p>12 A No.</p> <p>13 Q Okay. Let's turn to the third page,</p> <p>14 which is at the bottom is Bates-stamped page 342.</p> <p>15 A Okay.</p> <p>16 Q Are you with me?</p> <p>17 A Yes.</p> <p>18 Q And in the middle of the page, it says</p> <p>19 "European Laws."</p> <p>20 A Yes.</p> <p>21 Q And it says "Perspective of Campaign for</p> <p>22 Safe Cosmetics." You see that?</p> <p>23 A Yes.</p> <p>24 Q Now, the third paragraph, it says:</p> <p>25 "United States has much to learn from EU example.</p>	<p>1 says, they -- they have a list of banned</p> <p>2 ingredients, but they are, as is stated up above</p> <p>3 where J&J talks about it, these are ingredients</p> <p>4 that the vast majority would not be used in</p> <p>5 cosmetics, would never be used. Rocket fuel,</p> <p>6 industrial waste, petroleum streams, they're</p> <p>7 not -- this is not a cosmetics specific list.</p> <p>8 It's a list of, call them, toxic chemicals for</p> <p>9 the -- for easy shorthand, and then they just --</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q Well, just --</p> <p>12 A -- across the board banned them.</p> <p>13 So -- so these numbers, the nine versus</p> <p>14 the 1100 or 1300, is in no way representative of a</p> <p>15 difference in regulation.</p> <p>16 Q Well, to be clear, we're -- this is a</p> <p>17 J&J document. So when you say it's misleading,</p> <p>18 it's misleading in what way?</p> <p>19 A No, no.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 MS. FRAZIER: Object to form.</p> <p>22 MR. LOCKE: To be clear, it's a document</p> <p>23 found in J&J's files. Nothing indicates who</p> <p>24 authored this document.</p> <p>25 THE WITNESS: What I'm responding to is</p>

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<p>1 this quote about -- from the Campaign for Safe 2 Cosmetics. 3 BY MR. GOLOMB: 4 Q Okay. Well, are -- you're familiar with 5 the EU Cosmetic Directive? 6 A Yes. 7 Q And -- and are you saying that the EU 8 Cosmetic Directive, it does not regulate 9 cosmetics? 10 MR. LOCKE: Objection to form. 11 THE WITNESS: No. 12 MR. LOCKE: Beyond the scope. 13 THE WITNESS: That's not what I'm 14 saying. 15 BY MR. GOLOMB: 16 Q Okay. I thought that's what I heard you 17 say. 18 A No, no, no, no. No, no, I'm just saying 19 you can't -- the number about the banned 20 ingredients has -- is a completely 21 apples-and-oranges kind of argument. 22 Q Okay. So are you -- are you familiar 23 with similar laws in -- under Canadian law? 24 MR. LOCKE: Objection. 25 THE WITNESS: I'm less --</p>	<p>1 knowledge of the Canadian regulatory laws and 2 bodies. 3 A And I would not present myself as an 4 expert on that. That's why we have an 5 international department. 6 Q Okay. Well, did you -- did you prepare 7 your -- for your -- yourself in this deposition 8 consistent with topic 13? 9 MR. LOCKE: Objection to form. 10 THE WITNESS: Did I become an expert on 11 international -- 12 BY MR. GOLOMB: 13 Q That wasn't my question. 14 A -- regulations? No. 15 Q I didn't say anything about being an 16 expert. And the -- and the -- the topic 17 description doesn't say anything about an expert. 18 A I mean, I -- 19 MR. LOCKE: Objection to form. 20 THE WITNESS: I can comment on certain 21 aspects of European regulation. In some ways it's 22 stricter and in some ways it's not. 23 BY MR. GOLOMB: 24 Q Okay. Under -- if we go to page 343. 25 And you'll see -- are you there -- it refers to</p>
Page 1109	Page 1111
<p>1 MR. LOCKE: Beyond the scope. 2 THE WITNESS: Yeah, I'm less familiar 3 with Canadian. 4 BY MR. GOLOMB: 5 Q I'm sorry? 6 A I'm less familiar with the Canadian. 7 I'm aware of some of the cosmetic -- 8 Q Well, just to respond to Mr. Locke and 9 to your answer, in the -- to be sure that the -- 10 under topic 13, we let you know that we're going 11 to -- one of the topics that we're going to be 12 discussing is foreign regulatory bodies, and one 13 of those foreign regulatory bodies specifically 14 was Canada. 15 MR. LOCKE: Correct. Again, this is a 16 fact witness, not an expert witness. The issue is 17 what does PCPC know about this. She doesn't know, 18 as she testified. 19 MR. GOLOMB: Well, that was my question. 20 THE WITNESS: Well, when you're asking 21 about talc, you're asking about Canadian in 22 general. 23 BY MR. GOLOMB: 24 Q Yeah, I'm asking -- we're asking 25 about -- we're asking generally about your</p>	<p>1 cosmetic regulation in Canada. 2 A Okay. And I didn't get a chance to read 3 this yet. 4 Q Okay. Why don't you take a look at 5 that. 6 A Thank you. (Peruses document.) 7 MR. LOCKE: How much time is left on the 8 record? 9 THE VIDEOGRAPHER: 21 minutes. 10 THE WITNESS: Okay. 11 BY MR. GOLOMB: 12 Q So if you go to the bottom, do you see 13 where it says "Canadian laws"? 14 A Yes. 15 Q And it says, quote: "Canadian cosmetic 16 regulations, like European Union regulations, are 17 stricter than those in the United States." 18 Do you have sufficient knowledge of the 19 Canadian laws to either agree or not with that 20 statement? 21 MR. LOCKE: Objection. You're reading 22 the perspective of the Campaign for Safe 23 Cosmetics. 24 MR. GOLOMB: I'm reading from the 25 document.</p>

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<p>1 BY MR. GOLOMB:</p> <p>2 Q And I just read -- did I read that</p> <p>3 accurately?</p> <p>4 A It's -- well, it's a quote -- it is a</p> <p>5 quote from the Campaign for Safe Cosmetics.</p> <p>6 Q Right.</p> <p>7 A I think it's probably like Europe: In</p> <p>8 some ways they may be stricter, and in other ways</p> <p>9 they're not stricter. I mean, just as an example,</p> <p>10 colors are more high -- much more highly regulated</p> <p>11 in the U.S. than they are in Europe, and I believe</p> <p>12 in Canada. Sunscreens, again, are drugs in the</p> <p>13 U.S. They're -- in Europe, certainly they're</p> <p>14 cosmetic.</p> <p>15 So, I mean, there's a -- there's a</p> <p>16 tradeoff. Yes, there are certain ingredients that</p> <p>17 may be more restrictive, a few ingredients that</p> <p>18 are banned, but only a very few that are really</p> <p>19 used in cosmetics that are banned. So it's --</p> <p>20 there's a tradeoff.</p> <p>21 MR. LOCKE: I also want to note for the</p> <p>22 record, once again, we have an incomplete document</p> <p>23 missing Bates-numbered pages. There's a gap</p> <p>24 between 45 and 48.</p> <p>25 MR. GOLOMB: Well, we're not there yet.</p>	<p>1 says under "Our goal."</p> <p>2 A "Our goal: Ensure that any reform of</p> <p>3 cosmetic regulations results in requirements that</p> <p>4 are no more demanding than J&J's current</p> <p>5 practices."</p> <p>6 Q Okay. More demanding than J&J</p> <p>7 practices, does that help you with your</p> <p>8 understanding as to who it was that drafted that</p> <p>9 document?</p> <p>10 MS. FRAZIER: Object to form.</p> <p>11 MR. LOCKE: Objection. Beyond the</p> <p>12 scope, form.</p> <p>13 Don't answer that question.</p> <p>14 MR. GOLOMB: Don't answer it because</p> <p>15 why?</p> <p>16 MR. LOCKE: Because she's never seen</p> <p>17 this document. She can't speculate on -- it's not</p> <p>18 even an exhibit.</p> <p>19 MR. GOLOMB: Well, she can -- she can --</p> <p>20 MR. LOCKE: She's not going to</p> <p>21 speculate.</p> <p>22 MR. GOLOMB: She can say that "I don't</p> <p>23 know." It's not a proper instruction.</p> <p>24 MR. LOCKE: It is a proper instruction.</p> <p>25 Go ahead.</p>
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<p>1 MR. LOCKE: But it's not included in</p> <p>2 this document.</p> <p>3 MR. GOLOMB: Well --</p> <p>4 MR. LOCKE: That's my point.</p> <p>5 BY MR. GOLOMB:</p> <p>6 Q Take a look at page 44. 344, do you</p> <p>7 have that?</p> <p>8 A I don't have 4 -- no, I go from 43 to</p> <p>9 45.</p> <p>10 (A discussion was held off the record.)</p> <p>11 BY MR. GOLOMB:</p> <p>12 Q And this is namely in response to</p> <p>13 Mr. Locke's objection before about we don't know</p> <p>14 who prepared this document.</p> <p>15 So take a look at 344 -- and, I'm sorry,</p> <p>16 I don't have a copy of this -- and just see in the</p> <p>17 middle where it says "Our goal."</p> <p>18 MR. LOCKE: Let the record reflect that</p> <p>19 counsel has handed the witness a document with</p> <p>20 more pages than is in the exhibit number, and this</p> <p>21 one includes a 44.</p> <p>22 THE WITNESS: Okay. What are you asking</p> <p>23 me to --</p> <p>24 BY MR. GOLOMB:</p> <p>25 Q Yeah, just read -- read out loud what it</p>	<p>1 THE WITNESS: I -- I don't know who</p> <p>2 wrote it, no.</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Do you have page 345?</p> <p>5 A I do have 345.</p> <p>6 Q I'm sorry?</p> <p>7 A I do have 345.</p> <p>8 Q Right.</p> <p>9 MR. GOLOMB: Can we put up 345, please.</p> <p>10 BY MR. GOLOMB:</p> <p>11 Q The very last sentence there, it says:</p> <p>12 "The CTFA strongly opposes this attempt to remove</p> <p>13 the self-regulatory status of the cosmetic</p> <p>14 industry."</p> <p>15 Is that still the C -- the PCPC</p> <p>16 position?</p> <p>17 A No.</p> <p>18 MR. LOCKE: Okay. Just -- just for the</p> <p>19 record, this is referring to a 1973 bill that was</p> <p>20 introduced but not passed.</p> <p>21 MR. GOLOMB: Well --</p> <p>22 MR. LOCKE: Go ahead and answer.</p> <p>23 MR. GOLOMB: No, I -- I object to that.</p> <p>24 MR. LOCKE: This -- you're --</p> <p>25 MR. GOLOMB: That's not what it refers</p>

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<p>1 to.</p> <p>2 MR. LOCKE: You're reading a sentence at</p> <p>3 the end of a caption that says "The Eagleton</p> <p>4 bill," and it begins: "In 1973, Missouri Senator</p> <p>5 Thomas F. Eagleton introduced a landmark bill,"</p> <p>6 and then it continues.</p> <p>7 MR. GOLOMB: That -- there's a</p> <p>8 discussion of the bill, and then in a separate</p> <p>9 paragraph, it says: "CTFA strongly opposes this</p> <p>10 attempt to remove the self-regulatory status of</p> <p>11 the cosmetic industry."</p> <p>12 MR. LOCKE: Can you have your colleague</p> <p>13 bring up the whole paragraph so we can see</p> <p>14 entirely what's written there?</p> <p>15 THE WITNESS: It says "strongly</p> <p>16 opposed," past tense, and I think that was true in</p> <p>17 '73. Now we -- we favor new legislation. So, I</p> <p>18 mean, things have changed since then.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Okay. Let's go to page 348.</p> <p>21 Do you see that?</p> <p>22 A I have that one.</p> <p>23 MR. LOCKE: Just, again for the record,</p> <p>24 we're missing 46 and 47.</p> <p>25 BY MR. GOLOMB:</p>	<p>1 the scope.</p> <p>2 THE WITNESS: Apparently that's what --</p> <p>3 BY MR. GOLOMB:</p> <p>4 Q Correct?</p> <p>5 A -- the Campaign for Safe Cosmetics is</p> <p>6 saying.</p> <p>7 Q Okay. Well, that's what's included in</p> <p>8 this document from January 19, 2009, that's been</p> <p>9 produced by J&J.</p> <p>10 MS. FRAZIER: Object to form.</p> <p>11 MR. LOCKE: Object to form.</p> <p>12 (Counsel conferring.)</p> <p>13 MR. LOCKE: That's not a question.</p> <p>14 THE WITNESS: Mm-hmm.</p> <p>15 BY MR. GOLOMB:</p> <p>16 Q Let me just ask you about EUROTALC's</p> <p>17 involvement with the -- with the CIR report. Was</p> <p>18 there any involvement from the -- from EUROTALC?</p> <p>19 A I'm -- I'm trying to remember. I --</p> <p>20 when we looked, there were comments, and I'm</p> <p>21 trying to think if that was from IMA Europe or</p> <p>22 EUROTALC, and I think it was IMA Europe.</p> <p>23 Q Do you know who Michelle Wyart-Remy is?</p> <p>24 A I've heard her name.</p> <p>25 Q She's the Secretary General of EUROTALC?</p>
Page 1117	Page 1119
<p>1 Q Do you have page 348?</p> <p>2 A I do.</p> <p>3 Q Okay. At the very bottom of the page,</p> <p>4 it says: "The fox guarding the henhouse." Have</p> <p>5 you heard that -- that phrase used before?</p> <p>6 A About cosmetics or about life or --</p> <p>7 Q Generally.</p> <p>8 A Sure.</p> <p>9 Q And what is that -- what does it mean to</p> <p>10 you?</p> <p>11 MR. LOCKE: Objection to form, beyond</p> <p>12 the scope.</p> <p>13 THE WITNESS: I've never been asked to</p> <p>14 define it. I mean, it's -- someone guarding the</p> <p>15 henhouse is -- someone guarding something who is</p> <p>16 not the right person. I don't know. This is -- I</p> <p>17 mean, this is from the Campaign for Safe Cosmetics</p> <p>18 again.</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q Right. And -- and they're suggesting</p> <p>21 that in a -- in the self-regulatory world of</p> <p>22 cosmetics, that in this case the fox is guarding</p> <p>23 the henhouse, correct?</p> <p>24 A That's what --</p> <p>25 MR. LOCKE: Objection. Form. Beyond</p>	<p>1 A Yeah, I've heard that name.</p> <p>2 Q And do you know who -- who is Mark</p> <p>3 Ellis?</p> <p>4 A Mark Ellis is the -- I think he's the</p> <p>5 head, I don't know what his title is, but of IMA</p> <p>6 North America.</p> <p>7 (Exhibit No. 115 was marked for</p> <p>8 identification.)</p> <p>9 BY MR. GOLOMB:</p> <p>10 Q Okay. And let's take a look at the next</p> <p>11 document, which has been marked for identification</p> <p>12 as Exhibit 115. It's a Imerys document, 33243.</p> <p>13 And it's on EUROTALC and IMA -- they</p> <p>14 share a letterhead?</p> <p>15 MR. LOCKE: Objection to form.</p> <p>16 THE WITNESS: It looks like in this</p> <p>17 case, they are.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Okay. Have you seen this document</p> <p>20 before?</p> <p>21 A I don't believe so.</p> <p>22 Q Okay. Why don't you take a look at it.</p> <p>23 A Okay.</p> <p>24 Q Specifically the first two pages of the</p> <p>25 document, that's what I'm going to be asking you</p>

90 (Pages 1116 to 1119)

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<p style="text-align: right;">Page 1120</p> <p>1 about.</p> <p>2 A Okay. (Peruses document.)</p> <p>3 Q Okay. Does this -- first of all, does</p> <p>4 this help refresh your recollection as to whether</p> <p>5 or not EUROTALC had some participation in the CIR</p> <p>6 report?</p> <p>7 A I --</p> <p>8 MR. LOCKE: Objection to form.</p> <p>9 THE WITNESS: We saw reference to, in</p> <p>10 looking at the CIR, that they -- that they did</p> <p>11 offer to make a presentation, and that offer was</p> <p>12 declined.</p> <p>13 MR. LOCKE: I'm just going to say for</p> <p>14 the record, we're again missing pages in</p> <p>15 Exhibit 115. We start with 43, we have 44, and</p> <p>16 then we skip to 51. It's a nine-page letter, but</p> <p>17 we only have got three pages of Exhibit 115.</p> <p>18 BY MR. GOLOMB:</p> <p>19 Q Have you -- have you seen the document</p> <p>20 before?</p> <p>21 A I don't believe so.</p> <p>22 Q Okay. So this was not a -- a document</p> <p>23 that you reviewed to assist you in your --</p> <p>24 A I --</p> <p>25 Q -- preparation for the deposition?</p>	<p style="text-align: right;">Page 1122</p> <p>1 A No --</p> <p>2 MR. LOCKE: Objection to form,</p> <p>3 mischaracterizes testimony.</p> <p>4 THE WITNESS: No --</p> <p>5 MR. GOLOMB: I didn't mischaracterize.</p> <p>6 I asked her to correct me if I'm wrong.</p> <p>7 THE WITNESS: What I said was that we</p> <p>8 know from looking at documents earlier today that</p> <p>9 apparently -- well, let me say not apparently --</p> <p>10 it's on this, they offered to make a presentation.</p> <p>11 "Please note that IMA North America and</p> <p>12 EUROTALC are available to make a presentation at a</p> <p>13 public hearing." And I believe -- and I think it</p> <p>14 was a document from Dr. Alan Andersen, and he</p> <p>15 said, We're not going to --</p> <p>16 BY MR. GOLOMB:</p> <p>17 Q Thanks --</p> <p>18 A Yeah.</p> <p>19 Q Thanks, but no thanks.</p> <p>20 A Yeah.</p> <p>21 Q Okay. And do you know whether or not</p> <p>22 they in fact commented on the scientific</p> <p>23 literature review?</p> <p>24 A I think these are their comments on the</p> <p>25 scientific literature review.</p>
<p style="text-align: right;">Page 1121</p> <p>1 A I'm pretty sure not.</p> <p>2 Q Okay. So on -- on the second page of</p> <p>3 the document, which the last three Bates stamp</p> <p>4 numbers are 244, do you see at the top of the page</p> <p>5 it says "Specific Comments"?</p> <p>6 A Yes.</p> <p>7 Q It says: "IMA-NA's and EUROTALC's</p> <p>8 specific comments will either identify a section</p> <p>9 of the SLR" -- that's the scientific literature</p> <p>10 review?</p> <p>11 A Correct.</p> <p>12 Q -- "upon which we wish to comment and</p> <p>13 then address that section specifically, or we will</p> <p>14 offer more general comments on a specific topic."</p> <p>15 A Okay.</p> <p>16 Q And do you know whether or not they in</p> <p>17 fact did that?</p> <p>18 A I mean, I think they're just referring</p> <p>19 to their comments. So I guess we're got -- it</p> <p>20 looks like there's pages in between. So I -- I</p> <p>21 assume they did that. I mean, this is one page of</p> <p>22 their comments.</p> <p>23 Q Okay. I thought you said -- correct me</p> <p>24 if I'm wrong, I thought you said that EUROTALC</p> <p>25 declined to be involved.</p>	<p style="text-align: right;">Page 1123</p> <p>1 Q Beyond this.</p> <p>2 A You mean did they comment on further --</p> <p>3 Q Yeah.</p> <p>4 A -- documents? I want to say I think</p> <p>5 they may have.</p> <p>6 Q And were their -- were their comments</p> <p>7 accepted?</p> <p>8 A I -- I couldn't answer that. I mean,</p> <p>9 the only way you could answer that would be to</p> <p>10 look at versions of the report and everything,</p> <p>11 but, I mean, I assume these are kind of a sample</p> <p>12 of the type of comments that they made, and -- and</p> <p>13 they're pointing that they have some expertise</p> <p>14 on -- on the mineralogy topic.</p> <p>15 Q Okay. And the final document that I</p> <p>16 want to show you is -- now, the -- the -- what is</p> <p>17 the Cosmetic Toiletry and Perfumery Association?</p> <p>18 A That is the British trade association.</p> <p>19 Q And in this process of -- from the --</p> <p>20 from the time that PCPC first learned of the</p> <p>21 potential association between talc and ovarian</p> <p>22 cancer, has the CTPA, have they been involved at</p> <p>23 all in any of the -- the science or the</p> <p>24 presentations that have been involved?</p> <p>25 A Not that I recall. Again, I'm trying to</p>

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<p>1 remember for -- for NTP, and I don't think we</p> <p>2 contacted more than a couple of associations to</p> <p>3 have them sponsor time. It's not out of the</p> <p>4 question that CTPA was one of them.</p> <p>5 Q Okay. And --</p> <p>6 A But I don't recall that. I really don't</p> <p>7 recall.</p> <p>8 Q Okay. And do you know whether or not</p> <p>9 they asked to participate?</p> <p>10 A I -- I don't recall.</p> <p>11 Q Do you know -- do you know whether or</p> <p>12 not they asked to be included in any</p> <p>13 communications about -- on the issue?</p> <p>14 A Not that I remember.</p> <p>15 Q Okay. Let me show you a document which</p> <p>16 we'll mark as Exhibit 116.</p> <p>17 (Exhibit No. 116 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. GOLOMB:</p> <p>20 Q You'll be happy to know that this is the</p> <p>21 final document.</p> <p>22 It's the first time I saw you smile</p> <p>23 today.</p> <p>24 A That's probably true.</p> <p>25 Q Now, this is a letter from Steve</p>	<p>1 A Yes.</p> <p>2 Q And it says: "Unfortunately, we were</p> <p>3 never able to identify anyone who was</p> <p>4 knowledgeable about the issue, i.e., epidemiology,</p> <p>5 who was also prepared to say that the weak</p> <p>6 statistical associations reported in the</p> <p>7 literature can be completely ignored."</p> <p>8 A That's --</p> <p>9 Q Okay. Did you see any further -- any</p> <p>10 additional communication either before or after</p> <p>11 this letter between Mr. Phillipson and</p> <p>12 Dr. Gettings?</p> <p>13 A I did not.</p> <p>14 Q And is it your read of this that -- that</p> <p>15 Mr. Phillipson and the CTPA were trying to locate</p> <p>16 an expert to say that the -- the association</p> <p>17 between talc and ovarian cancer that is</p> <p>18 demonstrated in the studies that existed at the</p> <p>19 time, that they wanted some -- an expert to say</p> <p>20 that they should ignore it?</p> <p>21 MR. LOCKE: Objection. Asked and</p> <p>22 answered by your colleague, Mr. Meadows.</p> <p>23 THE WITNESS: They're trying to identify</p> <p>24 a spokesperson.</p> <p>25 BY MR. GOLOMB:</p>
Page 1125	Page 1127
<p>1 Gettings, the director of Toxicology, dated June 6</p> <p>2 of 1996, correct?</p> <p>3 A Yes.</p> <p>4 Q And do you know who Ian Phillipson is?</p> <p>5 A I don't.</p> <p>6 Q Do you know --</p> <p>7 A I mean -- oh, sorry.</p> <p>8 Q I'm sorry. Go ahead.</p> <p>9 A No, it's apparently someone who works at</p> <p>10 CTPA.</p> <p>11 Q Have you seen this document before?</p> <p>12 A I have. I saw it at my deposition that</p> <p>13 took place not yesterday, but the previous one.</p> <p>14 Q And this is -- this is a letter from</p> <p>15 Steve Gettings to Ian Phillipson.</p> <p>16 A Mm-hmm.</p> <p>17 Q And apparently the two of them were</p> <p>18 trying to connect but were unable to, correct?</p> <p>19 A Yes.</p> <p>20 Q And at least according to the letter, it</p> <p>21 says: "I understand you," meaning Mr. Phillipson,</p> <p>22 "needed to identify an independent spokesperson on</p> <p>23 the talc issue." Paren, "I presume the ovarian</p> <p>24 cancer issue."</p> <p>25 Did I read that correctly?</p>	<p>1 Q And that is to specifically address</p> <p>2 these -- the statistical association reported in</p> <p>3 the literature between the association between</p> <p>4 talc and ovarian cancer, correct?</p> <p>5 MR. LOCKE: Objection to form, and asked</p> <p>6 and answered.</p> <p>7 BY MR. GOLOMB:</p> <p>8 Q Correct?</p> <p>9 MR. LOCKE: Same objection.</p> <p>10 THE WITNESS: They were trying to</p> <p>11 identify a spokesperson to --</p> <p>12 BY MR. GOLOMB:</p> <p>13 Q And Dr. Gettings said, We -- we have no</p> <p>14 such person that can help you.</p> <p>15 MR. LOCKE: Objection. Mischaracterizes</p> <p>16 the document, and asked and answered.</p> <p>17 BY MR. GOLOMB:</p> <p>18 Q Okay. Well, let's quote from it.</p> <p>19 "Unfortunately, we were never able to identify</p> <p>20 anyone who was very knowledgeable about the issue,</p> <p>21 i.e., epidemiology, who was also prepared to say</p> <p>22 that the weak statistical association reported in</p> <p>23 the literature could be completely ignored."</p> <p>24 Did I read that correctly?</p> <p>25 A You read that correctly.</p>

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<p>1 MR. LOCKE: But you didn't read the next 2 page -- 3 THE WITNESS: Yeah. 4 MR. LOCKE: -- which your colleague did 5 before. 6 THE WITNESS: He does go on then to 7 suggest people that he could contact that might 8 be -- might be good. 9 BY MR. GOLOMB: 10 Q Okay. And that one of those people is 11 Dr. Wynder. 12 A Correct. 13 Q Who we've -- we've talked about, and 14 Dr. Wehner. Correct? 15 A We've talked about him a little bit, 16 Dr. Wynder, but not very much at all. 17 Q Well, we -- what we did talk about with 18 Dr. Wynder and Dr. Wehner, when you talked to me 19 about them, they were both people who -- who 20 suggested that industry and PCPC do independent 21 studies and their advice was ignored, correct? 22 MR. LOCKE: Objection to form. 23 THE WITNESS: I'm not -- I wouldn't 24 characterize it that way. And I think in this 25 letter, Steve Gettings is suggesting that these</p>	<p>1 MR. GOLOMB: Okay. That's all I have. 2 Thank you. 3 MR. LOCKE: We have no questions. 4 THE VIDEOGRAPHER: Okay. Any other 5 statements for the record? That's it? 6 MR. LOCKE: We want to read and sign. 7 THE VIDEOGRAPHER: Okay. 8 MR. GOLOMB: I don't know, we -- do we 9 have any more time? 10 MR. LOCKE: No. 11 THE VIDEOGRAPHER: One minute and 30 12 seconds. 13 MR. GOLOMB: One minute and 20 seconds. 14 THE VIDEOGRAPHER: All right. The time 15 is 5:18 p m., October 2nd, 2018. Going off the 16 record, completing today's videotaped session. 17 (Whereupon, the deposition of 18 LINDA LORETZ, Ph.D. was concluded 19 at 5:18 p m.) 20 21 22 23 24 25</p>
Page 1129	Page 1131
<p>1 might be people who could be spokespeople. So... 2 BY MR. GOLOMB: 3 Q So when you say you wouldn't 4 characterize it that way, you wouldn't have 5 characterized it as being ignored? 6 MR. LOCKE: Objection to form. 7 THE WITNESS: I'm not -- well, the 8 studies that were talked about were not done. 9 BY MR. GOLOMB: 10 Q Okay. And so when you say, I 11 wouldn't -- I wouldn't say it that way, you 12 wouldn't use my word "ignored"? 13 MR. LOCKE: Objection to form. 14 THE WITNESS: They were not done. 15 BY MR. GOLOMB: 16 Q Is that -- is that what you're raising? 17 A They were not done. 18 MR. LOCKE: Objection to form. 19 BY MR. GOLOMB: 20 Q So, in other words, they were -- in 21 fact, they weren't ignored. They were considered, 22 but the industry declined to do so. 23 MR. LOCKE: Objection to form. 24 THE WITNESS: I prefer that wording, 25 yes.</p>	<p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 The undersigned Certified Shorthand Reporter 3 does hereby certify: 4 That the foregoing proceeding was taken before 5 me at the time and place therein set forth, at 6 which time the witness was duly sworn; That the 7 testimony of the witness and all objections made 8 at the time of the examination were recorded 9 stenographically by me and were thereafter 10 transcribed, said transcript being a true and 11 correct copy of my shorthand notes thereof; That 12 the dismantling of the original transcript will 13 void the reporter's certificate 14 In witness thereof, I have subscribed my name 15 this date: October 4, 2018 16 17 _____ 18 LESLIE A TODD, CSR, RPR 19 Certificate No 5129 20 21 (The foregoing certification of 22 this transcript does not apply to any 23 reproduction of the same by any means, 24 unless under the direct control and/or 25 supervision of the certifying reporter)</p>

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Page 1132	Page 1134
<p>1 INSTRUCTIONS TO WITNESS</p> <p>2 Please read your deposition over carefully and</p> <p>3 make any necessary corrections. You should state</p> <p>4 the reason in the appropriate space on the errata</p> <p>5 sheet for any corrections that are made.</p> <p>6 After doing so, please sign the errata sheet</p> <p>7 and date it.</p> <p>8 You are signing same subject to the changes</p> <p>9 you have noted on the errata sheet, which will be</p> <p>10 attached to your deposition. It is imperative</p> <p>11 that you return the original errata sheet to the</p> <p>12 deposing attorney within thirty (30) days of</p> <p>13 receipt of the deposition transcript by you. If</p> <p>14 you fail to do so, the deposition transcript may</p> <p>15 be deemed to be accurate and may be used in court.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, _____, do hereby</p> <p>3 certify that I have read the foregoing pages, and</p> <p>4 that the same is a correct transcription of the</p> <p>5 answers given by me to the questions therein</p> <p>6 propounded, except for the corrections or changes</p> <p>7 in form or substance, if any, noted in the</p> <p>8 attached Errata Sheet.</p> <p>9</p> <p>10 _____</p> <p>11 LINDA LORETZ, Ph.D. DATE</p> <p>12</p> <p>13</p> <p>14 Subscribed and sworn to</p> <p>15 before me this</p> <p>16 _____ day of _____, 20____.</p> <p>17 My commission expires: _____</p> <p>18 _____</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p>Page 1133</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> <p>25</p>	

A	1054:16	821:16 870:18	1049:22	971:15
a.m 763:21	ACKNOWLEDGE ...	897:7	1050:13	1099:25
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Exhibit 133

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,
SPECIAL TITLE (RULE 3.55)

JOHNSON & JOHNSON TALCUM
POWDER CASES.

JCCP NO. 4872

AFTERNOON SESSION

REPORTER'S DAILY TRANSCRIPT OF PROCEEDINGS

AUGUST 10, 2017

Reporter:

CAROLYN GREGOR, CSR, CM, RDR, CRR
Certificate No. 2351
Court Reporter Pro Tempore

1 CASE NUMBER: JCCP 4872
2 CASE NAME: JOHNSON & JOHNSON
3 TALCUM POWDER CASES
4 LOS ANGELES, CA AUGUST 10, 2017
5 DEPARTMENT 307 HON. MAREN E. NELSON
6 APPEARANCES: (AS HERETOFORE NOTED.)
7 REPORTER: CAROLYN GREGOR, CSR 2351
8 TIME: 1:23 P.M.

9 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
10 COURT OUTSIDE THE PRESENCE OF THE JURY:)

11
12 THE COURT: Back on the record outside the
13 presence of the jury with all trial counsel here.

14 Mr. Robinson?

15 MR. ROBINSON: Yes, your Honor. We're not going
16 to call another live witness, your Honor. We will read
17 from a depo, but we are offering all of our exhibits in
18 evidence, and defense is objecting to some of our
19 exhibits. I think they already came in. I thought they
20 came in with Dr. Godleski. They are his slides. But he
21 put them, you know, into evidence.

22 But I do think we need to have a discussion on
23 these. I got a list about 10 minutes ago from defense
24 counsel of a list of exhibits that they don't want to --
25 that they are opposing, and I think -- I'm okay with them
26 starting the witnesses, your Honor, and I'm willing to
27 tentatively close our case subject to having the Court --
28 first of all, meeting with counsel on the admissibility

1 of our documents, the ones that they are not agreeing to
2 right now.

3 And then we can -- we also are going to be
4 reading in interrogatories, and we have agreed to that as
5 well.

6 THE COURT: And this is also subject to the
7 stipulation that you reached yesterday about the net
8 worth arrangements?

9 MS. ZUKIN: Yes, your Honor.

10 MR. WILLIAMS: Correct. And subject to that
11 agreement, yes, exactly.

12 MR. ROBINSON: So we have the net worth
13 agreement that we have to read in --

14 THE COURT: You don't have to read that in.
15 It's on the record.

16 MR. ROBINSON: It's on the record.

17 And then I told them on these slides I will take
18 out the language on the top of the exhibits. But I do
19 think we need to have -- I don't want to slow down what
20 they are doing. We don't intend to put on any more
21 witnesses, your Honor.

22 I think we could conditionally rest with the
23 understanding that these documents that we're still --
24 and we've been -- apparently this has gone on for a
25 couple days now. We haven't gotten an agreement on the
26 documents, your Honor. So --

27 MR. WILLIAMS: May I just explain briefly our
28 position? May I see that, please?

1 MR. ROBINSON: Yeah, these are them, and there
2 are some others too.

3 MR. WILLIAMS: The question is whether or not
4 documents come in as fully admitted exhibits that the
5 jury gets in the jury room or whether they are merely for
6 identification. And, for example, on the literature, the
7 parties did not agree that they would come in to be
8 admitted but rather for identification purposes.

9 The same with the demonstratives, the
10 photographs, for example, used by Dr. Godleski. Our
11 position is that those were for demonstrative purposes
12 and were not admitted fully.

13 And just for the record, they are Exhibit EE39A,
14 EE39B, EE40A, EE155, and EE39C. And those were all
15 discussed with Dr. Godleski.

16 We believe they can be shown in closing, they
17 can be discussed, but they shouldn't be fully admitted is
18 our position simply because they were photos that were in
19 his report. That's our position on that.

20 And with respect -- and we're happy to permit
21 plaintiff to close, subject to the Court ruling on those
22 things, just so we can get things moving. That's our
23 position on that.

24 With respect to the stipulation, there's one
25 stipulation regarding Exhibit P396 which we'd agreed
26 to --

27 THE COURT: I saw that.

28 MR. WILLIAMS: -- and we have no objection to

1 that being read.

2 And with respect to the interrogatories, we
3 tried to reach a stipulation but couldn't reach agreement
4 because there was language added that was not in the
5 interrogatory responses.

6 So I believe the plan is that Ms. Zukin is going
7 to read three interrogatories, the question and then the
8 answer that is the relevant portion of the answer. And
9 it's Answers to Interrogatories 2, 6, and 17.

10 MS. ZUKIN: Correct.

11 MR. WILLIAMS: And they've asked us whether we
12 would agree that -- to permit the Court to give CACI 209,
13 which is the use of interrogatories --

14 THE COURT: I was just getting out my CACI.

15 MR. WILLIAMS: And we're fine with the use of
16 that.

17 THE COURT: Okay. So we'll just use CACI 209.

18 MS. ZUKIN: We would request that the Court read
19 it before I read the interrogatories.

20 THE COURT: All right.

21 MS. ZUKIN: Thank you.

22 THE COURT: So what we will do when the jury
23 comes back, then, I think we should settle out this issue
24 about the exhibits later so that we can move on to other
25 things. But when the jury comes back, I will instruct
26 them on CACI 209, you'll read the interrogatories and the
27 answers to the interrogatories, plaintiff will
28 conditionally rest with the understanding that the

1 stipulation that you received yesterday may allow you to
2 reopen or not, depending upon how we end up on that.

3 And then how do you want to proceed?

4 MR. WILLIAMS: I would like at that point to
5 make an oral motion, your Honor, once they have closed,
6 conditionally, which will just take me a few moments.

7 THE COURT: Do you want to do that outside the
8 presence of the jury?

9 MR. WILLIAMS: Yes. It will take me three
10 minutes, I think.

11 THE COURT: Okay. He needs to make a record.
12 All right. Let's do that.

13 Do we have the jury back? Can someone go get
14 the jury?

15 MR. WILLIAMS: So I guess we will do those few
16 things and then --

17 THE COURT: And then we will excuse the jury.

18 MR. WILLIAMS: Thank you.

19 THE COURT: And then once your motion is heard,
20 I presume you have witnesses you're ready to call?

21 MR. WILLIAMS: Yes.

22 THE COURT: Okay.

23 MR. ROBINSON: Your Honor, we are going to give
24 you Stipulation Number 1. Mr. Williams and I both signed
25 this.

26 Do you want to read that?

27 MR. WILLIAMS: Sure.

28 MR. ROBINSON: May I approach, your Honor?

1 THE COURT: Sure. Are you going to read that
2 into the record or is it just on the exhibit?

3 MR. ROBINSON: It's on that one exhibit.

4 MR. WILLIAMS: I think it should be read into
5 the record.

6 THE COURT: Do we need to do that in the
7 presence of the jury?

8 MR. WILLIAMS: I don't know that it's necessary.
9 But whatever is the Court's pleasure.

10 MR. ROBINSON: I think I'm okay as long as it
11 gets read into the record.

12 THE COURT: Because the exhibit will go into the
13 jury room and then it will be there.

14 MR. ROBINSON: Yes, your Honor.

15 MR. WILLIAMS: That's right.

16 THE COURT: All right. So the stipulation of
17 counsel is that Exhibit P396 is a fax dated
18 September 30th, 2004, from Mr. Richard Zazenski,
19 Z-A-Z-E-N-S-K-I, of Imerys to Mr. William Ashton of
20 Johnson & Johnson.

21 Defendant Johnson & Johnson stipulates and
22 agrees that it received Exhibit 396 and has kept the
23 document within its company files since the time it was
24 sent.

25 That's the extent of the stipulation; correct?

26 MR. WILLIAMS: Yes, your Honor.

27 MR. ROBINSON: Yes, your Honor.

28 THE COURT: All right. And I'll ask the clerk

1 to file the stipulation.

2 MR. ROBINSON: Then if the Court will read 209.

3 THE COURT: And Ms. Zukin is going to read the
4 interrogatories and the answers to the interrogatories.

5 Do you have a copy of the interrogatories and
6 the answers, Ms. Zukin? Do you have extra copies?

7 MS. ZUKIN: Yes.

8 THE COURT: You might just give those to the
9 court reporter. Sometimes it's handy to have those when
10 somebody is reading something.

11 MS. ZUKIN: May I?

12 THE COURT: Yes.

13 THE REPORTER: Thank you.

14 COURTROOM ATTENDANT: They are coming, your
15 Honor.

16 THE COURT: Okay.

17 (A discussion is held off the record.)

18 THE COURT: And just so I'm keeping up, what's
19 the name of the first witness?

20 MR. WILLIAMS: Dr. Alan Andersen, S-E-N at the
21 end. A-L-A-N.

22 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
23 COURT IN THE PRESENCE OF THE JURY:)

24 THE COURT: All right. Back on the record with
25 all jurors here, both alternates here, all trial counsel
26 here. Let's proceed. Good afternoon, everybody.

27 ALL: Good afternoon.

28 THE COURT: Mr. Robinson, do you have any other

1 witnesses you'd like to call on behalf of the plaintiff?

2 MR. ROBINSON: At this point, your Honor, with
3 the understanding that there are exhibits to be offered
4 after we -- after the -- after we finish court today, the
5 plaintiff will rest conditionally on the Court ruling on
6 those documents.

7 THE COURT: Understood.

8 MR. ROBINSON: And we have to read in also the
9 interrogatory, and the Court's reading in the jury
10 instruction.

11 THE COURT: Right. So let me explain to the
12 jury about this piece of it. So before trial, each party
13 has the right to ask the other party to answer questions,
14 and those are written questions. And the questions are
15 called interrogatories. The answers come out in writing
16 and they are given under oath.

17 So Ms. Zukin is going to read the questions and
18 the answers. You should consider the questions and the
19 answers that are read in court the same as if the
20 questions and answers had been given in court by a
21 witness.

22 Everybody understand that idea?

23 ALL: Yes.

24 THE COURT: Okay. Ms. Zukin.

25 MS. ZUKIN: Thank you.

26 THE COURT: Hold on.

27 (A discussion is held off the record.)

28 THE COURT: Okay. Are you ready to go?

1 MS. ZUKIN: Yes.

2 All right. Good afternoon. I'm going to read
3 the answers by Johnson & Johnson and Johnson & Johnson
4 Consumer Companies, Inc., sometimes referred to in these
5 answers with the acronym JJCC.

6 The first one:

7 Question: State the corporate name of
8 defendant, any name under which defendant does business
9 including state of incorporation, date of incorporation,
10 if applicable, the names and addresses of all officers
11 and other principals of your organization and your
12 registered agent.

13 Answer: In response to the subparts requesting
14 corporate name, trade name, state of incorporation, and
15 date of incorporation, JJCC has been sued under its
16 correct name. JJCC is incorporated in New Jersey and
17 maintains its principal place of business in New Jersey.
18 JJCC was incorporated on March 23rd, 1967.

19 The second question: For each product you have
20 manufactured or sold that contained talc, state -- and
21 this is subpart 3 -- the first and last dates of sale of
22 each product.

23 Answer: In response to subpart 3, Johnson's
24 baby powder debuted in 1893 and remains on the market
25 today. Shower to Shower debuted in the 1960s and it
26 remains on the market today, although it is now
27 manufactured by Valeant Consumer Products.

28 The third question: Please describe the

1 business relationship between Johnson & Johnson and
2 Johnson & Johnson Consumer Companies, Inc., and provide a
3 detailed description of the corporate structure of
4 Johnson & Johnson and specifically how it relates to
5 Johnson & Johnson Consumer Companies, Inc.

6 Answer: JJCC states that it is a wholly owned
7 subsidiary of Johnson & Johnson and has been at all
8 times -- all relevant times. JJCC is incorporated in New
9 Jersey and maintains its principal place of business in
10 New Jersey.

11 Thank you, your Honor. That's it.

12 THE COURT: Thank you.

13 With that read into the record, and subject to
14 the stipulations that we have previously discussed, does
15 the plaintiff rest?

16 MR. ROBINSON: Subject to those stipulations
17 that we discussed previously, your Honor, plaintiffs
18 rest.

19 THE COURT: All right. Thank you.

20 Mr. Williams.

21 MR. WILLIAMS: Thank you, your Honor.

22 The defense calls Dr. Alan Andersen to the
23 stand.

24 THE COURT: All right. Good afternoon, sir. If
25 you would come up here and watch your step. After you
26 get your seat, the clerk will give you the oath.

27 THE CLERK: Sir, do you solemnly state that the
28 testimony you are about to give in the cause now pending

1 before this Court shall be the truth, the whole truth,
2 and nothing but the truth, so help you God?

3 THE WITNESS: I do.

4 THE CLERK: Thank you, sir. You may have a
5 seat.

6 Sir, would you please state and spell your name
7 for the record.

8 THE WITNESS: Alan, A-L-A-N, Andersen,
9 A-N-D-E-R-S-E-N.

10 THE CLERK: Thank you.

11 MR. WILLIAMS: Your Honor, may I approach with a
12 binder?

13 THE COURT: Yes.

14 * DIRECT EXAMINATION *

15 *[1:41 P.M.]*

16 Q BY MR. WILLIAMS: Good afternoon, Dr. Andersen.

17 A Good afternoon.

18 MR. WILLIAMS: Good afternoon, everybody.

19 ALL: Good afternoon.

20 Q BY MR. WILLIAMS: Dr. Andersen, did you
21 previously work at the Food and Drug Administration?

22 A Yes, I did.

23 Q And for how long?

24 A I spent 22 years at FDA.

25 Q Could you tell the members of the jury what
26 years those were.

27 A I started at FDA in 1971, and I worked there
28 until 1993.

1 Q After you worked at the FDA, did you work at an
2 organization called the Cosmetic Ingredient Review?

3 A Yes, I did.

4 Q Is that also known as the CIR?

5 A Yes, it's quicker to say.

6 Q How long did you work at CIR?

7 A I worked at CIR for 20 years.

8 Q What were those years?

9 A From '93, after I had left FDA, until I retired
10 in 2013.

11 Q Dr. Andersen, were you trained as a scientist?

12 A I was.

13 Q Could you describe for the members of the jury
14 briefly your educational background, starting at college.

15 A Okay. Well, I went to Muhlenberg College in
16 Allentown, Pennsylvania. I studied biology, and
17 somewhere along the line I got really super interested in
18 physics, so I kind of parlayed the two. I got my
19 bachelor of science degree in biology from Muhlenberg
20 college and then went on to graduate school.

21 Q What year did you graduate from college?

22 A Oh, now you're asking for memory. I believe it
23 was '66, 1966.

24 Q That's what I have, too.

25 And you received a BS or BA? What was your
26 degree?

27 A BS degree in biology.

28 Q After you graduated from Muhlenberg College,

1 what did you study next and where?

2 A I went further west in Pennsylvania to State
3 College and enrolled in the biophysics program at Penn
4 State.

5 Q what year did you graduate from the biophysics
6 program at Penn State?

7 A well, there were two milestones. One, in 1969,
8 I received my master's of science degree in biophysics,
9 and then in 1971 I finished my Ph.D. work in biophysics.

10 Q And where did you go next?

11 A I got a real job. I went from Penn State to the
12 U.S. Food and Drug Administration.

13 Q what was that year?

14 A 1971.

15 MR. WILLIAMS: Your Honor, can I have a moment?
16 I think I gave counsel my binder accidentally. I just
17 want to make sure I have the right binder now.

18 Thank you. Thank you.

19 Q BY MR. WILLIAMS: We were talking about your
20 Ph.D. program. That was at Penn State as well?

21 A That's correct.

22 Q And you received your Ph.D. in 1972?

23 A The ceremony didn't happen until '72, but
24 everything was finished in '71, and earning a salary
25 seemed like a good idea.

26 Q And the Ph.D. was in what area?

27 A Biophysics.

28 Q Can you describe what biophysics is?

1 A Oh, it's that marriage between biology and
2 physics. But in a simplified form, just about everything
3 that is biological follows the laws of physics as well.
4 So you can predict a lot about what's going to happen in
5 a biological system by knowing what's going to happen on
6 the physics side of it.

7 Just like hitting the brakes on your car is
8 supposed to stop your car. What stops an enzyme when
9 it's moving around in a cell? How does it spin? All of
10 that is governed by the laws of physics, and what we try
11 to do is to use that to better understand the biology.

12 Q In your training did you conduct any research on
13 cell mutations as they applied to cancer?

14 A Yes.

15 Q What did you focus on?

16 A Most of my work in graduate school was on the
17 effects of radiation, particularly ionizing radiation,
18 from radioisotopes. Things that could be incorporated
19 into cells. And that focus kind of shifted when I got to
20 FDA.

21 Q Did you go straight to the FDA after you
22 received your Ph.D.?

23 A I did.

24 Q What was the first position you held there?

25 A I was a researcher in the genetics study section
26 of the Division of Biological Effects of the Bureau of
27 Radiological Health. I can still remember that.

28 Q While you were at the FDA, did you participate

1 in conducting cell studies?

2 A Yes.

3 Q Were you involved in animal studies?

4 A Yes.

5 Q Did you supervise researchers who were doing
6 epidemiological studies?

7 A Yes, I did that too.

8 Q And in what -- how was it -- or in what way did
9 you supervise researchers who were doing epidemiological
10 studies?

11 A Okay. The -- the organization responsible for
12 doing all of the research and testing for
13 radiation-emitting products, X-ray machines, if you will,
14 and all medical products were located within what was
15 called an Office of Science and Technology.

16 And as the director of the Office of Science and
17 Technology, the epidemiology staff had to come to me and
18 convince me the study was well designed, worth doing,
19 before I'd say, "Do it." So it was a supervisory
20 responsibility over what work they were doing.

21 Q And approximately how many epidemiologists did
22 you supervise in that way?

23 A Oh, it usually was a staff of around 10.

24 Q After you were a researcher in the Division of
25 Biological Effects, what was your next position in FDA?

26 A Well, from a researcher, I went to supervisory
27 positions within that same organization. But then
28 finally I was recruited to take over a position at the

1 FDA's Bureau of Medical Devices.

2 Q What were your responsibilities in that role?

3 A I ran -- I was asked to run the standards
4 program. Medical devices are generally classified into a
5 group of regulatory controls, one of which is there
6 should be a standard that this medical device meets in
7 order to assure safety. In fact, that's most medical
8 devices.

9 I was the associate director of standards
10 responsible for all of those medical devices.

11 Q Let me move you to another role you had that may
12 have more direct relation to this case. Did there come a
13 point in time when you became the FDA director of the
14 office of Science and Technology?

15 A Yes.

16 Q Approximately when was that, give or take a few
17 years?

18 A Give or take a few years. '89, 1989, 1990 --
19 '89, I think.

20 Q And what were your responsibilities as the
21 director of the Office of Science and Technology?

22 A All of the engineering and research --
23 engineering testing, research conducted on both medical
24 devices and radiation-emitting products, microwaves,
25 sunlamps, X-ray machines. So it included the full range
26 of radiation products and the full range of medical
27 devices. We didn't do much research on tongue
28 depressors, but computerized tomography and more

1 technically advanced devices, there was a lot of research
2 being done.

3 Q In that role, did you have any authority over
4 how to deploy resources within the FDA?

5 A Yes.

6 Q Were there animal studies or human cell studies
7 or epidemiological studies involved with any of the work
8 that you did in that group?

9 A All of the above.

10 Q What types of specialties, that is --
11 specialists -- excuse me. What type of -- types of
12 specialists did you work with in terms of scientists,
13 physicians? Can you just describe them to the jury?

14 A I think I learned very early on that if you were
15 going to do well as a leader of the effort, you got the
16 best expertise working under you.

17 Toxicology was certainly a big part of the
18 staffing. Engineering because we had the large medical
19 device responsibility. We still maintained the
20 epidemiology research responsibility, so I had
21 epidemiologists on the staff. We had an animal care
22 facility so that we could house and work with the animals
23 in the animal studies.

24 Q Was pharmacology part of the group of
25 specialists underneath you?

26 A Yes, it was.

27 Q Were you also the chair of the FDA Regulatory
28 Review Scientist Peer Review Committee?

1 A Yes, I was.

2 Q Let me ask you a question about that. It's a
3 mouthful. But what is the Regulatory Review Scientist
4 Peer Review Committee all about?

5 A Okay. I described the kinds of things I did at
6 FDA, and that was moving through gradually getting
7 promoted in supervisory positions. And it was more and
8 more management responsibilities kept me going up the
9 ladder.

10 At the same time, there were a lot of FDA
11 scientists who had a benefit to the organization because
12 of their scientific knowledge. And, frankly, it would
13 have been a waste of their effort to, just for a
14 promotion, take their attention away from that science
15 and have to go manage something. Let them do what they
16 are good at. But the system wasn't designed to recognize
17 that. The system of promotions at FDA was designed to
18 get supervisory responsibility, you get a promotion.

19 So I had, in my own work with scientists under
20 me, gotten a few people around the system, just made a
21 strong enough argument so that the office of personnel
22 bought into it.

23 But the problem was hugely widespread at FDA.
24 So it came to a point where the personnel office and the
25 federal office of personnel management came to me and
26 said, look, you've had some success at doing this. Can
27 you make this a system? Define the characteristics of
28 what makes a regulatory scientist really good for FDA and

1 worthy of a promotion without having to take on any
2 supervisory responsibility.

3 And I did that. I developed that scheme and
4 implemented it.

5 Q So the gist of it was to figure out a way that
6 scientists could get promoted without necessarily being
7 supervisors?

8 A That's correct.

9 Q Did you hold any other positions -- and I'd like
10 to move you to the time when you were about to leave the
11 FDA -- what was the last position that you held there?

12 A I was the acting director of the Office of
13 Device Evaluation.

14 Q And what did you do in that role?

15 A Well, device evaluation is a place where all of
16 the industry submissions of scientific data supporting
17 their whiz-bang new medical device is actually safe and
18 effective.

19 So the Office of Device Evaluation was the group
20 that looked at all of those laboratory studies,
21 pre-clinical data, clinical data, submitted by
22 manufacturers to support the safety of medical devices.

23 Q How long did you have that role?

24 A I spent a year as the director of Office of
25 Device Evaluation.

26 Q So that would have been around 1992, just before
27 you left to go to the CIR?

28 A That's correct.

1 Q You went to the CIR or Cosmetic Ingredient
2 Review in 1993?

3 A That's correct.

4 Q How did it come about that you went to the CIR
5 after the FDA?

6 A I was recruited.

7 Q By whom?

8 A The -- an old colleague, an ex-FDA chief
9 counsel, Peter Hutt, reached out and wanted to know if I
10 might be interested in -- in a change of scenery. Peter
11 and Mr. Ed Kavanaugh, who was the president of the
12 Cosmetic Fragrance Association at the time, recruited me
13 to come take over this position.

14 The then director was retiring and they wanted
15 to bring in somebody with FDA regulatory experience to
16 head up this independent review group.

17 Q The CTFA the jury has heard about, the Cosmetic
18 Toiletry, Fragrance Association, is the CIR a government
19 agency?

20 A No, it's not; it's separate.

21 Q Did the FDA participate in the formation of the
22 CTFA?

23 A Yes, they did.

24 Q How was the CIR created?

25 A Well, the creation certainly predated me, but
26 the records are pretty clear. Circa 1976, the industry,
27 the Food and Drug Administration, and the Consumer
28 Federation of America met to talk about how could we do a

1 better documentation of the safety information that we
2 have regarding the ingredients that are used in
3 cosmetics? How would we do that?

4 And they looked at a number of alternatives
5 including, well, the FDA should do it. FDA opined that
6 it didn't have the resources really to do that.

7 Industry said, well, maybe we could support
8 financially creating an independent review group that
9 would look at it.

10 If you can picture the consumer groups at that
11 point saying, well, it has to be sure to be independent
12 because otherwise why would we trust it?

13 So you can see that dynamic going on.

14 In the final analysis, FDA said, if you can
15 create an independent review group to look at these data,
16 that will work. The Consumer Federation agreed with
17 that, and the industry, I think, swallowed hard because
18 they were going to have to pay for it, but the trade
19 association bought in as well, and CIR was created.

20 Q What is the mission of the Cosmetic Ingredient
21 Review?

22 A Well, it's been pretty constant for over 40
23 years now. Review and assess the safety of ingredients
24 used in cosmetics in an open, unbiased, and expert manner
25 and take the results and publish them in the
26 peer-reviewed scientific literature.

27 Q After moving to CIR, did you have a chance to
28 continue working with members of the FDA?

1 A I'm sorry. Say that again?

2 Q Sure. After you moved to the CIR -- and what
3 role did you have at CIR when you went?

4 A Oh, I was from day one the director of the
5 Cosmetic Ingredient Review.

6 Q From the time that you became the director of
7 the CIR, did you continue to work from time to time with
8 people who worked at the FDA in any capacity?

9 A Yes, in several capacities, not the least of
10 which is that, in having bought into this package of
11 creating the Cosmetic Ingredient Review, FDA continued to
12 participate in the process of actually reviewing the
13 safety of cosmetic ingredients by having a liaison
14 representative as part of the process. So there were
15 interactions on a regular basis with the FDA Office of
16 Cosmetics and Colors for that reason.

17 But, more frankly, the interactions with FDA
18 came from my involvement with the Food and Drug
19 Administration Alumni Association, and that brought me in
20 contact on a regular basis -- excuse me -- with folks
21 from all over the FDA. Certainly the Center for Food
22 Safety where cosmetics are -- are dealt with, but every
23 other center at FDA. So my contact level with FDA didn't
24 really decrease when I went to CIR.

25 Q You mentioned something in your last answer, the
26 Center for Food Safety relating to cosmetics. Can you
27 describe that? Because one is food and one is cosmetics.
28 How does that come about?

1 A There are oddities about how organizations are
2 titled all over the place. The overarching regulatory
3 authority that FDA works on is called the Food, Drug, and
4 Cosmetic Act. Cosmetics are in the title of the law.
5 There's no organization at the major breakdown level that
6 has cosmetics in its name. It was determined long ago,
7 and I don't know the genesis of the decision, that
8 cosmetics were most like foods, and that that's where the
9 organizational citing of the cosmetics program would be.
10 It's still called the Office of Cosmetics and Colors
11 because it has responsibility for ensuring the safety of
12 cosmetics and color additives. But it's located in the
13 Center for Food Safety and Applied Nutrition. If you
14 didn't know any better, you would never know that.

15 Q You mentioned a few minutes ago that Mr. Peter
16 Huff had previously been chief counsel at the FDA and
17 then had moved on to the CIR; is that correct?

18 A He had moved on to a position of outside counsel
19 with the CTFA.

20 Q In your professional experience, is it unusual
21 for government employees to leave government and go to
22 work in the private sector or to leave the private sector
23 and to go back to the government? Does that happen?

24 A It does. I haven't gone back the other way yet,
25 but it happens.

26 Q Is it unusual?

27 A No. It's -- it happens.

28 Q What were your responsibilities as director of

1 the CIR?

2 A Oh. Well, as I described to you the mission
3 statement, assess -- review and assess the safety. That
4 means gather the scientific information that are
5 available, seek out any unpublished scientific
6 information that might help figure out whether this is
7 safe or unsafe, and package that information in a way
8 that it can be reviewed by the members of the CIR expert
9 panel.

10 Q Let me ask you -- I'm sorry.

11 A Go ahead.

12 Q Let me ask you some questions about the
13 structure of the CIR in a minute.

14 A Okay.

15 Q But before I get there, in the course of your
16 work at CIR, did you review human cell studies?

17 A Yes.

18 Q Did you review animal studies?

19 A Yes.

20 Q Epidemiology studies?

21 A Yes.

22 Q Did you do that to assess the safety of various
23 substances that are contained in cosmetic products?

24 A Yes. Cosmetic ingredients.

25 Q Approximately how many cosmetic ingredients has
26 the CIR reviewed in its history?

27 A Over 5,000.

28 Q During your time as director, which was from

1 1993 -- and I'm sorry, I didn't get the end date --

2 A 2013.

3 Q From 1993 to 2013, approximately how many
4 cosmetic ingredients did CIR review?

5 A Probably 3,500 of those 5,000. Most of them are
6 under my tenure.

7 Q And after leaving the CIR in 2013, have you
8 continued to work?

9 A Yes, I have, sparingly.

10 Q Would you call yourself semi-retired?

11 A I think I'm fully retired with dipping my foot
12 in occasionally.

13 Q How often -- strike that.

14 what types of consulting do you do?

15 A I aligned with a consulting firm in Virginia
16 that provides the administrative support so that I don't
17 have to handle all of the paperwork part of it.

18 But the things that I've done have been working
19 on, advising a developing cosmetic company on how to
20 construct their labeling. I've done work through the
21 consulting company on a lawsuit concerned about radiation
22 leakage from electron microscopes, harkening back to my
23 radiation protection days. And I've gotten involved in
24 this litigation.

25 Q And you're referring to this talc litigation;
26 correct?

27 A That's correct.

28 Q So you've been retired since 2013. So

1 approximately going on four years now; is that right?

2 A Boy, it is four, yes.

3 Q And those -- you just listed the different
4 engagements that you had in that time?

5 A Yes. It wasn't my plan to do a lot. But it's
6 nice to keep your hand in.

7 Q Did Johnson & Johnson retain your services in
8 this case to discuss, among other things, the policies
9 and procedures and practices at the Cosmetic Ingredient
10 Review?

11 A Yes.

12 Q How much is Johnson & Johnson being charged for
13 your time?

14 A \$695 an hour.

15 Q Was that always the rate?

16 A No, it's -- last year it was 650. I'm not sure
17 what it was the -- well, let's see. This is 2017. And I
18 only started in 2016. So it was 650 in 2016, 695 this
19 year.

20 Q Have you been asked to provide an opinion
21 regarding an assessment as to whether talc is safe?

22 A Yes.

23 Q Have you been asked to do that to a reasonable
24 degree of medical certainty -- or scientific certainty?

25 A Well, scientific certainty.

26 Q Excuse me. I misspoke. Scientific certainty.

27 A Yes.

28 Q Have you been asked to give an opinion -- or to

1 describe, rather, the CIR review process that it
2 undertook regarding talc?

3 A Yes, that's -- that's the how-it-was-done part.

4 Q I'd like to shift gears and talk about the
5 process that CIR uses to assess or review ingredients in
6 a general way. And I assume that that general way that
7 it assesses ingredients would apply to talc as well; is
8 that right?

9 A Yes, there aren't two ways of doing it. There's
10 a way we do it, and that's how we do it.

11 Q Did you help to prepare a demonstrative to just
12 show the overall structure of the CIR?

13 A Yes.

14 MR. WILLIAMS: Your Honor, we've provided these
15 to counsel. This would be slide 2.

16 THE COURT: Counsel, have you seen the slide?

17 MR. SMITH: I don't have a problem with slide 2,
18 your Honor.

19 THE COURT: All right. Thank you.

20 MR. WILLIAMS: If we could publish that,
21 Mr. Bales.

22 Q BY MR. WILLIAMS: Over on the left, Doctor, it
23 talks about the steering committee. And it says "seven
24 members."

25 Could you describe for the members of the jury
26 whether CIR has rules that define the membership of the
27 steering committee, the seven-member committee?

28 A Yes. It's spelled out in very great detail in

1 the CIR procedures by which we operate.

2 Q when were those procedures put in place?

3 A Oh, they were done in 1976.

4 Q what is the makeup -- or is there any particular
5 makeup of the seven members of the steering committee?

6 A Yes, there is. It's -- most of the positions
7 are organizational. So, for example, the American
8 Academy of Dermatology, the physicians group in this
9 country that comprises dermatologists, appoints a member
10 to the steering committee. The Society of Toxicology,
11 one of the U.S -- well, international, really -- groups
12 of professional toxicologists, the Society of Toxicology
13 appoints a member to the steering committee.

14 The Consumer Federation of America -- I didn't
15 really describe them earlier, but the Consumer Federation
16 is an organization of consumer activist organizations
17 from around the country, public interest research groups
18 from all over, that band together to -- in an effort to
19 assure consumer interests are protected. The Consumer
20 Federation appoints a member to the steering committee.

21 Q You covered three positions. Is there a fourth
22 that is always a member of the committee?

23 A well, there's the -- the chair of the CIR expert
24 panel was made a part of the CIR steering committee.

25 Q So you've now listed four different positions.
26 Are there -- of the remaining three members, who sits on
27 the steering committee as the remaining three members?

28 A Okay. The other three members, it includes the

1 president now of the Personal Care Products Council,
2 because it changed its name from CTFA. It includes the
3 vice president for science at the Personal Care Products
4 Council, and it includes -- I think it's always been an
5 industry person, but the companies change -- an industry
6 scientist who chairs the trade association's CIR Science
7 and Support Committee.

8 Q So there are four -- excuse me, strike that --
9 there are three members from industry, four members from
10 the scientific community?

11 A That's correct.

12 Q Is that intentional?

13 A Very much so.

14 Q Why?

15 A The decisions made about any changes in policy
16 direction, decisions made about who should be appointed
17 to the CIR expert panel, if there's a vacancy, those
18 should be made by a group that is mostly not industry.

19 Q How are the CIR activities funded?

20 A The Personal Care Products Council pays the
21 bills.

22 Q Do they fund the salaries of the people who are
23 the full-time employees of the CIR?

24 A Yes, they pay the salaries.

25 Q How about the members of the steering committee?
26 Are they paid?

27 A You know, oddly enough, no. All the members of
28 the steering committee in their work, they've always done

1 it just because it's a good thing to do.

2 Q You mentioned that one of the members of the
3 steering committee is also the chairperson of the expert
4 panel.

5 A That's correct.

6 Q Could you describe for the members of the jury
7 the membership of the expert panel and how that works.

8 A Okay. well, the panel of experts -- expert
9 panel -- is a group of nine individuals with medical and
10 scientific backgrounds who are charged with looking at
11 the -- the data that are available on each cosmetic
12 ingredient that's being reviewed. And they do that at
13 meetings several times a year, and then they come back
14 and repeat it again because there's a lot of cosmetic
15 ingredients.

16 Q How long do the members of the expert panel
17 serve in that capacity?

18 A The CIR procedures call for a six-year
19 appointment, and the procedures say that's renewable
20 once. And then it says, after that, we'll look and see.

21 Q Are the members of the expert panel that works
22 for -- strike that.

23 Are the members of the expert panel, those nine
24 people, are they paid?

25 A Yes, they are paid.

26 Q What are they paid?

27 A They're paid an hourly rate for the work that
28 they do reviewing material in preparation for each panel

1 meeting. And that's significant because it's, you know,
2 not like somebody handing me this binder. It's boxes
3 full of scientific material that they are getting to look
4 at in preparation for an upcoming meeting.

5 So they spend their time with that information,
6 reviewing it. And they keep track of their hours. And
7 they submit a time sheet to the CIR afterwards. For each
8 of the days that they spend at the meeting, they also get
9 paid an hourly rate.

10 Q The CIR and the PCPC offices at the time that
11 you were last working at the CIR, were they in the same
12 office suite or building, or how was the setup?

13 A Well, it changed while I was there. When I left
14 in 2013, the CIR suite was on a different floor -- in the
15 same building, but on a different floor -- from the trade
16 association.

17 Q Did that fact, the fact that they were in the
18 same building on different floors, affect the
19 independence of the CIR in reviewing?

20 A No. The CIR procedures specifically flagged the
21 issue of the CIR program is to be an independent program.

22 So I don't know how much of a measure it is of
23 independence, but whenever someone from the trade
24 association visited the CIR offices, they had to sign in
25 and state the purpose of their visit, just like they were
26 any other non-CIR individual. So it was a way of keeping
27 track of what was happening and help ensure the
28 independence.

1 Q Other than the sign-in procedures that you just
2 described, did the CIR take any other steps to ensure
3 that the CIR acts independently of industry with respect
4 to conflicts of interest and the like?

5 A Well, conflicts of interest is -- is a piece
6 that was, again, in the procedures very specifically
7 applied to the members of the expert panel.

8 Panel members are required to not have any
9 conflicts of interest. They can't consult for cosmetic
10 companies. They are to have no financial interest in
11 that group of products that are being regulated -- wrong
12 word. I keep putting on my FDA hat -- that are being
13 evaluated by the Cosmetic Ingredient Review program. And
14 those -- that information is provided.

15 Thankfully, we stayed away from forms, but panel
16 members are to tell me about what their interests are and
17 certify that they don't do any work for the cosmetics
18 industry.

19 Q Let's talk about the expert panel, the
20 nine-person panel. What does the expert panel do?

21 A Oh, they review that ton of material at each of
22 their meetings and assess what they think it means.

23 Q Are there any members of industry on the
24 nine-person expert panel?

25 A No, there aren't.

26 Q How is the expert panel -- how are the members
27 chosen to be on the expert panel for the CIR?

28 A Well, at the beginning, and then any time a

1 vacancy occurs, there's an open public process by which
2 nominations are sought. The word goes out to scientific
3 societies, medical groups, certainly consumer interest
4 groups, "Here's what we're looking for in terms of expert
5 scientists and physicians. Can you please nominate
6 somebody whom you think would be good to serve in this
7 capacity."

8 And those nominations are collected. And it's
9 the steering committee that makes the decision on who is
10 to be selected.

11 Q Did your expert report list the nine members of
12 the expert panel who were sitting in the nominee expert
13 panel at the time that talc was reviewed by the CIR? Did
14 you list those names in your report?

15 A In my expert report? No, I don't think I did,
16 actually.

17 Q Can you recite the names of those folks?

18 A Oh, yeah.

19 Q Did you help us to prepare a slide with the
20 names of the individuals and their photographs?

21 A Yes.

22 MR. WILLIAMS: Your Honor, permission to publish
23 slide 3 from the package that we gave counsel.

24 THE COURT: Mr. Smith?

25 MR. SMITH: No objection, your Honor.

26 THE COURT: Thank you.

27 Q BY MR. WILLIAMS: If you would, Dr. Andersen,
28 start with the first person listed here, which is

1 Dr. Wilma Bergfeld, B-E-R-G-F-E-L-D. And if you would,
2 for the members of the jury, describe the professional
3 background, starting with Dr. Bergfeld.

4 A Okay. I can do that.

5 Wilma Bergfeld is a dermatologist. She's also a
6 dermatopathologist. She runs the dermatopathology
7 program at the Cleveland Clinic. Wilma is a practicing
8 dermatologist, the first woman ever to be the president
9 of the American Academy of Dermatology. She still works
10 two times a week in the pathology lab looking at slides,
11 evaluating and feeding back to the physicians, was this a
12 cancer, not a cancer, benign cancer, malignant cancer.
13 Looking at tissue samples and reporting back is a big
14 part of her responsibility at the Cleveland Clinic.

15 Q Let me stop you there. Was Dr. Bergfeld the
16 chairperson of this panel during the time that talc was
17 reviewed?

18 A Yes, she was.

19 Q And therefore, was she the person who also sat
20 on the steering committee at the CIR as well?

21 A That's correct.

22 Q Could we move now to James Marks, Jr.

23 A Jim Marks is also a dermatologist. At the time
24 that the talc safety assessment was done, Jim was the
25 chair of dermatology at the Penn State Medical School in
26 Hershey, Pennsylvania. Jim's expertise is primarily in
27 contact dermatitis, how the skin reacts to anything that
28 contacts it.

1 He also is a major force behind the North
2 American Contact Dermatitis Group, which is a consortium
3 of high-level physicians across the country that run
4 essentially a monitoring service of, whoa, what's new in
5 terms of what we're seeing in the population as far as
6 upcoming adverse effects on the skin? So it's a
7 monitoring effort. And Jim was very good about keeping
8 all of us in touch with what the medical community
9 actually knows currently.

10 Q Let's move to Donald Belsito, M.D., at Columbia
11 University Medical Center.

12 A Okay. Don is also a dermatologist. His
13 specialty is in immune-related diseases. Psoriasis would
14 be an example. And his expertise in terms of both the --
15 looking at human disease that extends beyond just looking
16 at the skin, as some of these diseases go further than
17 just the surface.

18 Q Next is Daniel Liebler, L-I-E-B-L-E-R, Ph.D.,
19 from Vanderbilt University School of Medicine.

20 A Okay, Dan is the director of the Ayers Precancer
21 Detection and Treatment Unit that -- at Vanderbilt's
22 School of Medicine. He's also a college -- professor of
23 pharmacology, biochemistry, and biomedical informatics.
24 His research relates to what are the mechanisms by which
25 things are carcinogenic.

26 Q Next is Ronald Hill, Ph.D., from the College of
27 Pharmacy at the University of Louisiana at Monroe. Could
28 you just describe --

1 A Okay. Ron is a medicinal chemist. And that was
2 important to bring onto the panel because CIR had found
3 itself dealing with a large number of cosmetic
4 ingredients that were derived from botanical sources, and
5 that -- those ingredients are almost always mixtures, and
6 it wasn't always clear what was in them.

7 Ron Hill's background in medicinal chemistry was
8 focused on: Okay, how do I deal with these mixtures?
9 what happens to them when they get in the body? what
10 kind of transformations do they undergo? what kind of
11 transformations do they cause? And that turned out to be
12 a rather important addition to the panel's expertise.
13 It's certainly chemistry but a focus on medicinal
14 chemistry.

15 Q Next is Curtis Klaassen, K-L-A-A-S-S-E-N, Ph.D,
16 from the School of Medicine at the University of Kansas.

17 A Okay. I mean, Curt is overall a toxicologist.
18 I mean, his subspecialties include pharmacokinetics, a
19 question of what does happen and how is it processed once
20 it gets in the body? But, overall, he's just well
21 recognized as a leader in the toxicology community.

22 You've heard it said that, you know, when you
23 describe somebody's expertise, he wrote the book. Curt
24 wrote the book -- probably the most widely used
25 toxicology textbook is Curt's textbook.

26 Q Next is Paul Snyder, DVM. What does "DVM" stand
27 for?

28 A Doctor of Veterinary Medicine.

1 Q And he is a Ph.D. as well?

2 A That's correct.

3 Q At the Experimental Pathology Laboratories. Why
4 a veterinarian on the board?

5 A Well, all of that bulk of data that the panel
6 receives includes a bunch of animal studies. And having
7 somebody -- and certainly Paul is a veterinarian but his
8 particular specialty is veterinary pathology. So his
9 expertise allows him to look at those studies and make
10 evaluations of what -- of how it was done, what the
11 findings are, and what the interpretations legitimately
12 should be. His Ph.D. was in immunology, which adds a
13 little bit more of that expertise to the CIR expert
14 panel.

15 Q Two more. One, Dr. Thomas Slaga -- is that how
16 you pronounce that? -- from the University of Texas.

17 A Yes.

18 Q Describe his background.

19 A We used to call Tom "Mr. Carcinogenesis." Tom
20 has been involved in studying mechanisms of
21 carcinogenesis for some 50 years now. He's headed cancer
22 treatment centers. I don't know what the acronym stands
23 for -- AMC Cancer Research Center in Colorado. For a
24 while, he headed the cancer treatment center at the
25 University of Texas Health Science Center in San Antonio
26 until he backed off to have more time doing his research.

27 But his background expertise is in the
28 mechanisms by which cancer is caused. He started the

1 journal Molecular Carcinogenesis so that there was a way
2 to get more of these studies published in the scientific
3 literature.

4 Q And finally, Ronald Shank, S-H-A-N-K, Ph.D.,
5 he's professor emeritus from the Department of Medicine
6 from UC Irvine. Can you describe his background.

7 A Okay. Ron, about the time when we were working
8 on talc, moved to his emeritus status. He had been the
9 director of the environmental health sciences program at
10 the department of medicine at UC Irvine. He created that
11 program. I'm not sure when it started, but he was the
12 guy that started it as an overarching program to train
13 scientists in how to evaluate any health concerns
14 relating to environmental pollution. So it included how
15 do you look at human studies? How do you look at cell
16 studies?

17 His own particular research, like others on the
18 panel, was on actually the mechanisms of carcinogenesis.

19 Q Great. Thank you. So what are the
20 classifications that the CIR uses to reflect its
21 assessment of the safety of ingredients contained in
22 cosmetics? What are the different categories or
23 classifications that exist?

24 A Okay. Well, the -- again, it's all spelled out
25 in --

26 Q And let me stop you again. Did you prepare a
27 slide that lists those categories?

28 A I think we have one, yes.

1 MR. WILLIAMS: Your Honor, permission to publish
2 slide 4.

3 MR. SMITH: No objection.

4 THE COURT: Thank you.

5 Q BY MR. WILLIAMS: If you would, Dr. Andersen,
6 just describe what each of these categories mean.

7 A Okay. Well, safe means that, after looking at
8 all of the available information, the panel determined
9 that it was perfectly okay to use this ingredient in
10 cosmetics. Almost always -- and safe is a one-word way
11 of saying it -- but almost always the panel says safe in
12 the present practices of use and concentration, because
13 the package that they're presented provides a background
14 on how this ingredient is actually used in cosmetics. Is
15 it used in creams and lotions? Is it used in sprays?
16 How is it used and at what concentrations?

17 So they have that information at hand and have
18 increasingly over the years -- I think I pushed them in
19 that direction -- have added that statement of "safe" and
20 look at the report to see how it's used and at what
21 levels it's used. So that's the safe category.

22 Q Dr. Andersen, are you familiar with the -- you
23 mentioned that there are approximately 5,000 ingredients
24 that have been reviewed in the history of the CIR.

25 A Yes.

26 Q Are you familiar with the data that would
27 reflect how many or what percentage of the ingredients
28 that have been reviewed that have fallen into these

1 different categories?

2 A Yes, I am.

3 Q How are you familiar with that?

4 A I get updates from the CIR staff on what the
5 numbers look like.

6 Q With respect to the category you just described,
7 the safe category, approximately what percentage of the
8 ingredients that have been reviewed have fallen into that
9 category?

10 A 42 percent.

11 Q Could you describe the next category, "Safe with
12 qualifications."

13 A Okay. "Safe with qualifications," well, it is
14 pretty much what that says. This ingredient, the panel
15 found, can be used safely in cosmetics if -- and then
16 comes the "if." Many of those ifs are, it's okay to use
17 in a product that's going to be rinsed off, but don't use
18 it in a product that's a leave-on product.

19 Some of those qualifications are, don't use it
20 above a given concentration. So put a limit on the
21 concentration of the ingredient that can be used.

22 There are qualifications that talk about
23 ensuring that the consumer is alerted to a particular
24 issue. So you've actually included in -- well, I don't
25 know -- I guess in a couple now -- specific language that
26 said that the qualification should include providing
27 warning information to a user.

28 Q What percentage of the ingredients that have

1 been reviewed by the CIR have fallen into the "safe with
2 qualifications" category?

3 A It's virtually -- you know, 56 1/2 percent.
4 Almost -- it's almost all of the rest.

5 Q And let's talk about the "unsafe" category.
6 Approximately how many ingredients have been identified
7 as unsafe by the CIR based on its review in its history?

8 A I think CIR's -- I don't think anything new that
9 I can recall. So we're up to 13 ingredients that have
10 been identified as unsafe for use in cosmetics. It's
11 about 1 percent. Let's see, 5,000 -- I can't do the math
12 in my head.

13 Q Now, 5,000 products reviewed, only 13
14 ingredients found to be unsafe. To what do you attribute
15 that relatively small number?

16 A Oh, I -- I don't see it as a small number.

17 Q Explain.

18 A The expectation is that ingredients used in
19 cosmetics are safe. That's kind of the mindset that you
20 ought to have going into this. And I feel pretty pleased
21 that we were able to identify 13 ingredients that said
22 get them the heck out of cosmetics. That's an important
23 accomplishment from my standpoint.

24 Q The final category is "insufficient data." What
25 does that mean for purposes of the review panel?

26 A It -- it means that, as much information as we
27 gathered and try as we would, it just isn't enough
28 information on which to make a determination. And we

1 can't say it's unsafe; we can't say it's safe. We can't
2 even put a qualification on it. We just don't know
3 enough. And --

4 Q Let me stop you there. If something is put into
5 the insufficient data category, can it go there forever,
6 or is there any time limit by which something has to be
7 done about it to take it out of the insufficient data
8 category?

9 A Yes. I think -- I mean, insufficient data is
10 kind of -- you're left hanging. So what happens next?

11 The CIR procedures specify that a two-year clock
12 starts. And within that time frame, any interested
13 party -- I mean, it talks about any interested party.
14 The message is, "Dear industry, provide us the data.
15 It's your ingredient; give us the data."

16 And if, at the end of those two years, the data
17 are not provided, it moves into a category that says
18 "should not be used in cosmetics."

19 Q And let me stop you there. In the insufficient
20 data category, I take it that's about 1 percent as well?

21 A Yeah, it's the remaining.

22 Q Okay. What category was talc placed in after
23 the CIR conducted its review of talc?

24 A Talc is in the safe category.

25 Q During the -- and that was on the basis of --
26 what -- how long -- from the time talc was first reviewed
27 or put up for review to the time that a CIR report was
28 prepared, how much time elapsed?

1 A In your question were you referring to
2 preparation of an initial report or a final report?

3 Q Well, let me be more specific.

4 I'm going to ask you in a minute how it came to
5 be that talc was reviewed. But before we get there, from
6 the point in time where talc was put up for review to the
7 point in time when a final report was done by the CIR on
8 talc, how much time elapsed approximately?

9 A About a year and a half.

10 Q With respect to the safe evaluation for talc
11 that ultimately occurred, was there -- was this a close
12 call based upon your years of experience?

13 A That's an interesting question. It sure didn't
14 seem like it. The panel was -- was very clear in their
15 evaluation of the data and that it supported the safe in
16 the present practices of use and concentration
17 conclusion.

18 Q Let me ask you a question about those
19 ingredients that have been rated or categorized over the
20 years in categories other than the safe category, so safe
21 with qualifications or unsafe.

22 In those situations where an ingredient was
23 listed as either safe with qualifications or unsafe, were
24 there industry representatives making comments that they
25 believed the ingredients should be listed as safe?

26 A It did not occur. I mean, self-interest is a
27 powerful thing, and folks would make comments. But the
28 focus of the CIR expert panel discussions is -- is just

1 so uniformly on the science that the opinion issue
2 doesn't really come to play.

3 Q For each of the products that have been
4 categorized as unsafe -- strike that.

5 For each of the ingredients -- excuse me -- that
6 have been categorized as unsafe or as safe with a
7 qualification, I take it there was an industry behind
8 that ingredient and product that was seeking a safe
9 evaluation? would that be accurate?

10 A My perception of the industry participation over
11 my 20 years is just slightly different spin than you are
12 phrasing it.

13 Q Please go ahead.

14 A The industry input is best categorized as
15 wanting to get to the right answer. I mean, yes, there
16 was self-interest that was expressed at times, saying "I
17 want this to be safe." But, by far, the tenor of the
18 input over my 20 years there was, let's get to the right
19 answer.

20 Q Let's move into the review of talc. Did the CIR
21 specifically review and consider whether talcum powder is
22 safe for use in the perineal area by women?

23 A Yes, that was part of the safety assessment.

24 Q Does the CIR have a set procedure for reviewing
25 the safety of an ingredient?

26 A Yes, we do.

27 Q Did the CIR apply those rules and procedures to
28 its review of talc?

1 A Yes.

2 Q How is it that talc came to be selected for
3 review, and when did that occur?

4 A Okay. The CIR expert panel is assigned the
5 responsibility of establishing the priorities for review.
6 Nobody else. It's -- the panel says, "This is going to
7 be our top priority for review."

8 They use a number of factors in making that
9 determination, but right at the top of the list is how
10 frequently is this ingredient used in cosmetics. And the
11 panel has that at the top of the list because that's
12 likely an indicator of how many people are going to be
13 exposed. So that's important.

14 Q Was the -- was the CIR provided a list of the
15 approximate number of products that contain talc in
16 making the assessment that you just described?

17 A Yes. The U.S. Food and Drug Administration
18 maintains a Voluntary Cosmetic Registration Program,
19 VCRP. And companies submit information on their use of
20 ingredients to FDA, and FDA captures all of that
21 information. And each time CIR does a safety assessment,
22 FDA provides that information to CIR on the -- on the
23 types of products and the -- the frequency in that
24 product category.

25 Q Approximately how many products contained talc
26 at the time a decision was made to review talc?

27 A I couldn't give you that number unless I looked
28 at the table.

1 Q Okay. Let me see if I can refresh your memory.
2 would looking at the CIR report itself help to refresh
3 your memory?

4 A Okay. The safety assessment.

5 Q In that notebook in front of you, there's an
6 exhibit -- it should be marked as Exhibit L384.

7 A Got it. Okay.

8 Q Do you have that there?

9 A I do.

10 Q And if you would --

11 And don't publish this, Mr. Bales. This is just
12 to refresh his memory.

13 If you turn to page 5 of L384, it should have it
14 there.

15 A Yeah, I've got it. It's the total number of
16 uses reported was 3,469.

17 Q Was that 3,469 number of products containing
18 talc the primary factor that pushed the CIR to review the
19 safety of talc?

20 A Yes, it was.

21 Q Approximately when was it that CIR decided it
22 would review talc?

23 A CIR had initially put it as a priority in 2009.
24 And then, unfortunately, I lost a staff person who was
25 working on it, so it went into a bit of a limbo. And
26 then I assigned it to a new staff person who began work
27 in late 2011. And she worked on it continuously until
28 its completion.

1 Q who was that staff member?

2 A Monice Fiume.

3 Q would you spell that, please?

4 A M-O-N-I-C-E, F-I-U-M-E.

5 Q what is Ms. or Dr. Fiume's --

6 A Ms.

7 Q -- Ms. Fiume's educational background?

8 A Bachelor of science degree and a master's
9 degree. She had worked doing animal testing and research
10 before she came to CIR.

11 Q Did the decision to review talc by the CIR
12 relate to numbers of claims, publicity, anything of that
13 kind relating to talc?

14 A No, it didn't.

15 Q Had talc ever been reviewed before by the CIR?

16 A No.

17 Q Have there been occasions where a request has
18 been made to the CIR to have a particular ingredient
19 reviewed?

20 A well, yes, there have been.

21 Q Can you give us an example?

22 A Probably the most requests for CIR to
23 immediately start something and do a safety assessment
24 have come from FDA. FDA didn't ask us to review talc,
25 but FDA has asked to review ingredients of --
26 formaldehyde and methylene glycol is used in
27 hair-straightening products. FDA asked the panel to
28 review alpha hydroxy acids that are used in skin lotions

1 and are supposedly to help smooth out your skin.

2 I would have to go back and see if I can come up
3 with others -- they were --

4 Q That's all right.

5 A It's not infrequent, but it's not frequent
6 either.

7 Q Were there any requests by the FDA or any other
8 organization for a review of talc by the CIR?

9 A No.

10 Q Had the CIR ever received requests that a review
11 of talc should be accelerated because of any safety
12 concern for talc?

13 A No.

14 Q What's the next step after naming an ingredient
15 to be put on the priority list for review -- what is the
16 next step that has to happen?

17 A Once it's assigned as a priority ingredient, you
18 begin to gather the data.

19 Q And how were the scientific data compiled in
20 this case?

21 A Searching through as many scientific search
22 engines as you can use to find what information has been
23 published.

24 We had the advantage in this circumstance of
25 also involving Dr. Ivan Boyer who was a toxicologist on
26 the CIR staff. Ivan and Monice worked side by side to --
27 to really harvest the information from whatever source we
28 could find.

1 Q Is there some formal name that's given to the
2 group of materials that were compiled in this case by
3 Dr. Boyer and Ms. Fiume?

4 A Yes, CIR calls it a scientific literature
5 review.

6 Q And what is that?

7 A Well, it's that collection and description -- I
8 mean, it's a bibliography at the end which says here's
9 what we looked at. But in the text it describes what
10 each of these studies was, what it did, and what it
11 found. No value judgments; it just presents what the
12 study was and what the findings were.

13 And it breaks those out into some logical
14 organization. Cell studies are bunched with cell
15 studies, animal studies with animal studies, epidemiology
16 is with epidemiology. And that literature review is --
17 we call it published. I mean, it's put on the website,
18 and the notice is, this is available -- freely available
19 to anybody that wants it for public comment. There's a
20 60-day public comment period. So any interested party
21 can review what we came up with for the scientific
22 literature.

23 Q Let me stop you there. I'm sorry to cut you
24 off. Let me just ask a question.

25 Once the scientific literature review package is
26 pulled together, can panel members, members of the review
27 committee -- the nine folks that you listed earlier --
28 can they ask for more information?

1 A They haven't seen it yet. So at that stage,
2 they wouldn't be asking for more information. Their shot
3 comes at the next step.

4 Q You indicated that the scientific literature
5 review package, that compilation, you said that it's made
6 public. Can outsiders -- industry, academia, consumer
7 groups -- can others weigh in on the data selection?

8 A Everybody.

9 Q Did that happen in the case of talc?

10 A I mean, not in a substantial way. We did get
11 input but from a very narrow sector.

12 Q Was there industry input on the -- the universe
13 of literature that was compiled?

14 A I think we received from one source a
15 bibliography of here's what we found. You know, here you
16 are, CIR.

17 Q Are those submissions made public?

18 A Yes.

19 Q Was the entire scientific literature review data
20 made public?

21 A Yes. It's the hallmark of the CIR process that
22 everything is going to be made public.

23 Q And when you say "everything," you're referring
24 in this case to the specific literature review that is
25 the universe of materials?

26 A The literature review. Since the comments we
27 receive aren't published anyplace, we make all the
28 comments public. So it's a process that celebrates the

1 openness.

2 Q After that 60-day comment period that you
3 referenced, what happens next?

4 A All of the -- any input that CIR received is
5 incorporated with the original scientific literature
6 review, and what we call a draft report is prepared.
7 It's still really just that presentation of the available
8 science, but it now has added to it anything that -- that
9 we've received.

10 And that draft report, two things happen. One
11 is that it's published on the website. So, again, any
12 interested party can look at it. It's part of the agenda
13 for an upcoming CIR expert panel meeting.

14 And then it goes both to any interested party,
15 because it's on the website, and, in particular, at this
16 point in time, we had just started doing --
17 electronically providing material to the panel. So they
18 were getting it all at the same time.

19 Q Let me stop you there.

20 Did the PCPC provide information to -- that was
21 included in the scientific literature review package?

22 A Not in front of preparing the scientific
23 literature review, but in response to the scientific
24 literature review, we received input from the trade
25 association.

26 Q Do you remember any specific type of data that
27 they provided, the PCPC?

28 A Oh, to be honest, most of it reads like typos.

1 But, you know, you'd get a comment that said that you had
2 a guinea pig study that you included in the
3 single-dose-exposure part of your report, but it also
4 looked for cancer, so please also mention it in the
5 cancer section.

6 That's good input. It helps make sure that, as
7 you read the report, nothing gets mixed. So that it's
8 either typos or highly technical comments on the science.

9 Q Do you recall when it was that the scientific
10 literature review was made public?

11 A August 2012, I think. The day in August, I
12 don't remember.

13 Q And you mentioned already the 60-day comment
14 period. Did there come a point in time when the draft
15 report was prepared?

16 A Yes.

17 Q When was that?

18 A That was November of 2012.

19 Q Who prepared the draft report?

20 A Monice Fiume, Ivan Boyer, and Al Andersen.

21 Q That's you; right?

22 A Yep.

23 Q Were there comments received in response to the
24 draft report?

25 A Yes, I think we did get some comments.

26 Q And I got ahead of myself. Was the draft report
27 made public?

28 A Yes, it was put on the CIR website as a PDF.

1 And anybody that wanted to download it could download it
2 and look at it.

3 Q When was the first meeting of the actual expert
4 review panel after that draft report was prepared?

5 A December of 2012.

6 MR. WILLIAMS: Your Honor, I was about to go
7 into that meeting. Would this be an appropriate time?

8 THE COURT: It would. Let's take a 10-minute
9 recess, stand up and stretch. Leave your notes here and
10 please take a short recess with the usual admonitions in
11 mind.

12 *[2:59]*

13 (Jurors excused.)

14 (Brief recess taken.)

15 THE COURT: All right. Back on the record with
16 all jurors here, the witness on the stand.

17 Go ahead, Mr. Williams.

18 MR. WILLIAMS: Thank you, your honor.

19 *[3:14]*

20 Q BY MR. WILLIAMS: Dr. Andersen, just before the
21 break we had moved through time and had just gotten to
22 the point where the first expert panel meeting relating
23 to talc occurred.

24 Do you have that time frame in mind?

25 A Yes, I do.

26 Q When was it that the first expert panel meeting
27 took place?

28 A December of 2012.

1 Q How often does the expert panel meet each year?

2 A The panel meets four times a year.

3 Q And at each one of those meetings, over what
4 period of time does it occur? One day? Two days? Three
5 days?

6 A Each meeting is a two-day meeting.

7 Q So there are eight days in a given year that the
8 entire expert panel meets together?

9 A That's correct.

10 Q Does the expert panel consider multiple
11 ingredients at a time?

12 A Yes.

13 Q Are the expert panel meetings open to the
14 public?

15 A They are.

16 Q Are the meetings recorded?

17 A They are.

18 Q Could you explain generally how an expert panel
19 meeting is run.

20 A Yes, I can.

21 Q Please do.

22 A On the first day of a CIR expert panel meeting,
23 something I instituted, I break the expert panel into two
24 teams, and they each separately review all of the
25 material. Scientists can be as competitive as anybody
26 else. And it's an approach that really pushes each of
27 these two review teams to do their best job they can at
28 assessing the available information.

1 And on day one of the meeting, each of the
2 review teams goes through everything separately.

3 Q At the conclusion of the first day -- strike
4 that.

5 Do the two teams spend the entire first day in
6 their separate groups?

7 A Yes. I mean, sometimes one team will make it
8 until five o'clock. Another team might actually finish
9 by a little before 4:00. They work at slightly different
10 paces, but, yeah, they spend the whole day at it.

11 Q Before the members of the expert review panel
12 come together for those meetings, what types of materials
13 have they received and how long have they had them?

14 A We usually ask that question in terms of how
15 many boxes that we send them. It's just -- it's
16 everything. It's the draft report, which is usually the
17 least of it.

18 Any unpublished data that Monice and Ivan and I
19 had included in that draft report, the panel got the full
20 unpublished data. The panel developed the practice of
21 telling us, "Don't send us the published studies."
22 Because, frankly, we're all back home here at academic
23 institutions and it's really easy to do one of two
24 things: either just get on the internet and pull up
25 the study, because our access at the library allows us to
26 just do that; or, we can get a copy printed out from the
27 university library.

28 So they said, "Don't send us the published

1 studies; we'll get those on our own."

2 But we have to send them the unpublished data
3 because they're unpublished. I mean, nobody else has got
4 them. So they get all of that to look at. They get
5 whatever input was provided to CIR from outside -- all
6 those comments on the SLR, the comments themselves were
7 provided to the expert panel so that they could see what
8 was said and, arguably, could act as a quality control on
9 CIR. So if CIR said, "well, I don't think this change is
10 needed technically," the panel can look at what was
11 suggested and say, "CIR, make the change."

12 So it provided everybody with all of the
13 information.

14 Q So taking us back to the meeting, we went
15 through the first -- got through the first day. What
16 happens at the second day of the meeting?

17 A The second day, the full panel convenes, all
18 nine people. And, one by one, they go through the safety
19 assessments that were on the agenda for that meeting.

20 Q Who presides at that meeting on the second day?

21 A Dr. Wilma Bergfeld runs the meetings.

22 Q As CIR director, did you attend the expert panel
23 meetings?

24 A Yes.

25 Q And I'm asking relating to talc, of course. Did
26 you attend --

27 A Well, I attended every one, talc or not.

28 Q Did you review all of the material that had been

1 provided to the expert panel?

2 A Yes.

3 Q Did you participate in the discussions with the
4 expert panel?

5 A I did.

6 Q Did you have a vote?

7 A No, I don't have a vote, but I get to talk.

8 Q What happened at the December 2012 expert panel
9 meeting -- I'm directing your attention to the second
10 day -- with respect to talc?

11 A I can't -- I'd have to really look at the
12 transcript to see which team moved to declare that talc
13 was safe in the present practices of use. But it's
14 usually one of the team leaders makes a motion and the
15 other team leader seconds it.

16 And then they go into a discussion of anything
17 that they think needs to be said regarding the motion to
18 reach a conclusion. And that's usually substantial.
19 "Here is what we want to see in the discussion."

20 They don't sit there in the meeting and actually
21 write the discussion, but they do talk about what they
22 want to see in the discussion that supports their
23 decision to reach this tentative conclusion.

24 And in our parlance, that tentative conclusion
25 is an important step. It's not done. We're tentatively
26 saying this is what we think the right answer is for this
27 particular ingredient or ingredient group.

28 Q Is that tentative conclusion that you just

1 referenced something called a tentative safety
2 assessment?

3 A That's correct.

4 Q The tentative safety assessment for talc was
5 published approximately when in 2012?

6 A Ten days after the meeting, so December 18th or
7 so. I'm not sure I remember the exact day, but it was
8 mid-December of 2012.

9 Q Is there a comment period after the tentative
10 safety assessment is prepared?

11 A Yes. Again, that's part of the procedures.
12 There's an opportunity -- a 60-day comment period for
13 anybody that wants to provide input to CIR.

14 Q Did the expert panel receive comments on the
15 tentative safety assessment?

16 A Yes, we did.

17 Q Did it receive comments from industry?

18 A Yes.

19 Q What sorts of comments?

20 A A lot of comments, most, again, highly
21 technical, relating to how things were organized and what
22 study should be put where. There were technical comments
23 on one particular study on cocarcinogenesis of a chemical
24 called benzo[a]pyrene. And in the draft report, the
25 staff and the panel had used a description of the assay
26 involved that was really quite old.

27 And the technical comment came in from the trade
28 association that, in fact, there was newer information

1 available about how you think of this as a potential
2 cocarcinogen.

3 And the trade association recommended that we
4 just delete all reference to that because it was no
5 longer relevant. That's an example of the kind of input
6 that was received.

7 Q Did all of the information that the CIR received
8 from industry become available to the public?

9 A Yes.

10 Q How, if at all -- or how would you characterize,
11 Dr. Andersen, the impact that industry comments had on
12 the evaluation being conducted by the expert panel?

13 A On the evaluation, not much. I mean, it's
14 always useful if somebody can find a technical issue that
15 ought to be fixed or improved. As I think of it, that
16 doesn't really impact on the actual evaluation; that just
17 improves the quality of the document. You know, a
18 comment -- another comment I recall we received was, "You
19 should really expand" -- the comment wasn't "expand" --
20 the comment was, "You should change how you describe what
21 talc is."

22 And you know, we read that, and we looked at
23 what they were saying, and, yes, this is another way of
24 describing the structure of talc and explaining why it
25 actually works to reduce friction. But the -- the
26 chemist on the CIR staff said that's -- that's not the
27 right way to do it and our way was wrong; it's just
28 another way of saying it.

1 So, yeah, it seemed like a good compromise. But
2 that -- that doesn't rise to the level of saying, did it
3 influence our evaluation? No, I don't think we received
4 much input that really influenced the evaluation.

5 Q Was there a final draft report that went to the
6 public? And, if so, when was it published?

7 A Okay. Well, that's -- that's the next step. So
8 we're in December of 2012, and we've issued this
9 tentative safety assessment with a 60-day clock. Talc
10 was scheduled to be reviewed at the March 2013 meeting,
11 which, you know, in preparing for the meeting meant that
12 sometime early February, we really wanted to hear from
13 any interested party so we could provide that information
14 to the expert panel.

15 Nobody is ever timely. We got some -- I mean,
16 not unsubstantial, but we got some input by the deadline
17 we had set, because we got to package this stuff, put it
18 in boxes, and sent it off to the panel again for them to
19 review it. We got some information that came in very
20 late. And in the panel's lovely parlance, it developed a
21 life of its own. There was a wave two package of
22 documents. And, again, it was a lot easier this time
23 because we were doing everything electronically. So
24 there was a draft -- you know, I should back up. I'm not
25 being as clear as I otherwise could have.

26 In response -- we've got the tentative safety
27 assessment. We receive input. What Monice and Ivan and
28 I did was take all of that input and prepare a draft

1 final, because that's going to be the next step. The
2 draft final then is part of this electronic package that
3 goes out to the panel. All the comments go out to the
4 panel. And then, wave two, all of the comments that came
5 in late go out to the panel. But all of that's on the
6 website, the comments. The panel has it, the public has
7 it. Nothing is not public.

8 Q Let me stop you there for a moment. Is there
9 any point in time when the members of the panel actually
10 provide line edits on any of these draft reports that we
11 have been discussing?

12 A Oh, they provided line edits at each of the
13 stages. When we sent them that draft report in December,
14 I could have a red ink franchise for the comments that
15 come back of providing us input. I mean, it's not
16 negative input. It's, you know, this is what I think of
17 this study. This is, you know, my particular expertise.

18 That then occurred on the draft final safety
19 assessment that we sent out in preparation for the March
20 meeting. Every chance they get, a draft -- a report,
21 they mark it up.

22 Q So do you remember the date of the March meeting
23 that you just referred to?

24 A Uh --

25 Q Sometime in March of 2013.

26 A Yeah. No, I don't remember the actual days.

27 Q And that was the second expert panel meeting
28 relating to talc?

1 A That's correct.

2 Q Did -- is there an opportunity for members of
3 the public or industry to speak at that meeting?

4 A Yes, they're open public meetings.

5 Q Did industry members speak at that second
6 meeting, the March 2013 meeting?

7 A Yes, there were industry representatives who
8 spoke.

9 Q Do you recall who spoke?

10 A No.

11 Q Do you recall how long they were given to speak?

12 A Oh, it turns out that -- at this meeting, there
13 were no formal presentations. As part of the panel
14 discussions, there were questions about information that
15 the panel had asked to come in from industry, and there
16 was dialogue about what is this we got, what does it
17 mean, et cetera.

18 So industry, as any member of the public, is
19 actually invited to participate in the open panel
20 discussion. It's not just the panel; it's anybody that
21 wants can participate, preferably after they've raised
22 their hand and asked permission. But it's a
23 participatory process, and there were some industry
24 inputs during that.

25 Had somebody asked for time to make a formal
26 presentation, that time would have been granted. And I
27 think I usually recommended that that be no longer than
28 an hour, preferably less.

1 Q Mr. Bales, could we publish page 3 again, which
2 is the listing of the expert panel members again.

3 Dr. Andersen, did the comments that were
4 received by the expert panel -- either in the first step,
5 the draft report, or the draft final report -- did the
6 comments from industry or members of consumer groups,
7 whatever, in your view, impact the CIR expert panel's
8 evaluation in any way?

9 A Not in my view.

10 Q Was there a vote taken ultimately as to the
11 approval for that final report that was prepared?

12 A Yes, it was unanimous.

13 Q When was that vote taken?

14 A The second day of the meeting in March,
15 whichever day that was.

16 Q After that vote -- strike that.

17 At the time that vote is taken, is the report in
18 a final form or there's work to be done still after the
19 second meeting?

20 A There's work to be done still. The panel
21 discussion almost always includes some element of
22 tweaking of the discussion section that they had
23 reviewed, not so much in the body of the report, but the
24 discussion section is just always tweaked to some extent.

25 And each panel member, again, has done their
26 markups of technical comments. And the routine statement
27 is, "well, yes, I've made technical comments on the
28 document. I'm very comfortable. The CIR staff can just

1 deal with those technical comments. They aren't anything
2 that we need to discuss as a full panel."

3 Just about everybody goes through that litany.
4 All the panel members make some version of that piece of
5 input. And then they reserve their time for talking
6 about the things that they actually think are significant
7 to talk about.

8 Q Was there any discussion at the second meeting,
9 the March meeting from 2013, regarding the use of talc on
10 broken skin?

11 A Yes, that was a discussion.

12 Q Can you relate that to the jury.

13 A Well, from the very beginning, the panel had
14 acknowledged that there is information that suggests that
15 if talc is applied to an open wound, that there is the
16 possibility that a granuloma can form. The panel didn't
17 consider that a significant finding of concern because
18 talc is just not applied to skin that has got an open
19 wound on it.

20 But the panel really wanted to mention that and
21 they did so. And they talked about, "Just how do you say
22 it?" And it turns out it's not as easy to say as you
23 would think it is. I mean, the concept was if the skin
24 is intact, you're home free. Now, how do you talk about
25 skin not being intact?

26 Q Did the final report include the discussion of
27 the language that was ultimately worked out with respect
28 to granulomas?

1 A That's correct. It did.

2 Q When was it that the final report was actually
3 buttoned up and put in final form?

4 A I think it was about a week and a half, no more
5 than two weeks after the meeting.

6 Q Let me ask you to take a look at Exhibit L384 in
7 your binder.

8 A Okay. That's what we just did, yeah.

9 Q Is Exhibit L384 the final version of the report?

10 A It's the final final version.

11 Q Okay.

12 A You know, I described earlier the mission of the
13 CIR kind of at the end of it was that phrase "and publish
14 in the peer-reviewed literature." well, the CIR safety
15 assessment that was late -- mid-March of 2013 was the
16 final CIR safety assessment. And that was published on
17 the website. And anybody who wanted to look at it can
18 look at it. So the final safety assessment was done.
19 But we have one more step. And that is the
20 organization's commitment to publishing it in the
21 scientific literature.

22 Not everybody knows to go to the CIR website to
23 get this information. And we were committed to
24 publishing it so that as many people as possible would
25 have access to it. That's what this document is.

26 Q So the final report was published on the website
27 in 2013; am I right?

28 A That's correct.

1 Q And the final final, as you've described it, is
2 the document in front of you, L384, which was published
3 in 2015?

4 A That's correct.

5 Q Was it published in the International Journal of
6 Toxicology?

7 A That's correct.

8 Q Is that a well-regarded scientific publication?

9 A That's a -- I think it's well regarded. For us,
10 one of the hallmarks of submitting for peer review at the
11 International Journal of Toxicology is the first word,
12 "international." We really like to get this word out
13 as -- just widely as possible so that anybody who wants
14 can see what we have done and agree, disagree. But at
15 least we get out this information so that it's widely
16 available. And international seemed like a really good
17 idea.

18 Q And take a look at the first page of Exhibit
19 L384.

20 And no need to publish it, Mr. Bales.

21 I just want to establish the authors of the
22 final report. I see a number of names there. Can you
23 describe -- you don't have to list the names, but just
24 describe who the people were as -- from categories who
25 are actually listed as authors of the final report.

26 A Okay. Well, it's -- it's Monice Fiume and Ivan
27 Boyer who did most of the heavy lifting. It's all of the
28 members of the CIR expert panel because they put their

1 scientific imprimatur on it. And it's me because I was
2 orchestrating the whole thing.

3 Q And that is it? It's the seven -- excuse me --
4 the nine folks who are on the board, the two staff
5 members, and yourself?

6 A Yes. I hope it adds up to 12. It's supposed
7 to. Nine and three, yes.

8 Q Did you help to prepare a demonstrative that
9 states the conclusion that was set forth in the CIR final
10 report?

11 A I believe I did.

12 MR. WILLIAMS: Your Honor, permission to publish
13 slide 5?

14 THE COURT: Mr. Smith?

15 MR. SMITH: Can I take just a second, your
16 Honor?

17 THE COURT: Yes.

18 MR. SMITH: Thank you.

19 No objection.

20 THE COURT: Thank you.

21 MR. WILLIAMS: If we could publish that,
22 Mr. Bales, slide 5.

23 No, 5. This one here.

24 I can use the ELMO. Just switch over. My
25 apologies.

26 Q BY MR. WILLIAMS: Dr. Andersen, is this the
27 conclusion that was reached by the CIR panel?

28 A That is the conclusion they reached.

1 Q Could you read your slide.

2 A "The CIR expert panel concluded that talc is
3 safe for use in the present practices of use and
4 concentration as described in the safety assessment."

5 Q Do you still have Exhibit L384 in front of you?

6 A Yes, I do.

7 Q Could you turn to the end of that document and
8 tell the members of the jury the number of references to
9 literature that are listed there.

10 A There are 218 citations.

11 Q Dr. Andersen, in the published report which was
12 published in the International Journal of Toxicology, did
13 the CIR explain its rationale for its conclusion that
14 talc is safe?

15 A Yes, it did.

16 Q Did the report set forth in summary fashion
17 the -- its reasoning?

18 A Yes, it did.

19 Q Did it do that in bullet point form and in text
20 form?

21 A It did it both ways, yes.

22 Q Have you prepared a slide that sets forth in
23 bullet point form the bases for the conclusions?

24 A Yes, I did.

25 MR. WILLIAMS: Your Honor, permission to publish
26 page 9 of the slides we provided?

27 THE COURT: Any objection?

28 MR. SMITH: No objection.

1 THE COURT: Thank you.

2 Q BY MR. WILLIAMS: And if you would, Mr. Bales,
3 let's pull out the top half if we can, just to make it so
4 it's a little bit bigger, if there's any way to make it
5 bigger.

6 At the top, Dr. Andersen, it says "critical
7 issues that called into question the validity" -- can you
8 folks read that, the top line?

9 THE COURT: Can everyone see that?

10 Q BY MR. WILLIAMS: It says, "critical issues that
11 called into question the validity of the statistically
12 significant associations."

13 what is that referring to?

14 A The panel had spent page after page after page
15 going through the available epidemiology studies that
16 looked for an association between talc and ovarian
17 cancer. And this is now, at the end of all of that,
18 "Here is what we think."

19 Q The first thing that's listed here is "absence
20 of persuasive evidence that talc can migrate from the
21 perineum to the ovaries."

22 And would it be accurate to say that there are
23 some studies that say talc could migrate, some could not?
24 Is that accurate?

25 A Well, I think that was certainly the sense of
26 the CIR expert panel. They had the view that --

27 MR. SMITH: Object, your Honor. This is
28 hearsay. I mean, if he wants to state personal

1 knowledge -- I mean, this is the expert panel. And it
2 says what it says in the report. Hearsay.

3 THE COURT: Sustained.

4 Q BY MR. WILLIAMS: Let me ask you, based upon the
5 review that you heard and the studies that you saw cited,
6 what is your view on the issue of migration?

7 MR. SMITH: I'm going to object. We haven't
8 established that he has gone through and done all the
9 review of migration. It's the expert panel, he said, did
10 all this.

11 THE COURT: Sustained.

12 Q BY MR. WILLIAMS: Dr. Andersen, did you
13 participate in the discussion of the expert panel with
14 respect to each of the nine bullet points that are
15 appearing on the screen?

16 A Yes, I did.

17 Q Did you read the studies that supported all of
18 the discussion that took place at both the initial
19 meeting of the panel and the second meeting?

20 A Yes.

21 Q Were you present --

22 A I do that with every safety assessment.

23 Q Were you present for all of the discussion as it
24 related to migration that occurred?

25 A Yes.

26 Q Did you read studies relating to it?

27 A Yes.

28 Q What was your view regarding the issue of

1 migration?

2 MR. SMITH: I'm going to object, your Honor, as
3 outside the scope of his report. This is not in his
4 report.

5 MR. WILLIAMS: Actually, this bullet point that
6 I'm asking Dr. Andersen about is in the report, your
7 Honor. I think it's on page --

8 MR. SMITH: If he can show it to me, that's
9 fine. I don't have a problem. I could be mistaken.

10 THE COURT: Bear with us for just a minute,
11 folks.

12 MR. WILLIAMS: Your Honor, it's on page 54 of 64
13 of Exhibit L384. It's the very first bullet point.

14 MR. SMITH: Excuse me. That's the CIR report?

15 MR. WILLIAMS: Correct. It's Exhibit L384.

16 THE COURT: I think Mr. Smith is making a
17 reference to Mr. Andersen's litigation report.

18 MR. SMITH: That's correct.

19 MR. WILLIAMS: Oh, I'm talking about Exhibit
20 384.

21 THE COURT: I think Mr. Smith is talking about
22 the report that Mr. Andersen wrote.

23 MR. WILLIAMS: Oh, understood. I understand.
24 It's Dr. Andersen.

25 THE COURT: Sorry.

26 Q BY MR. WILLIAMS: Dr. Andersen, did you in your
27 report discuss the -- did you incorporate by reference
28 the CIR report in your report?

1 A Um --

2 Q In other words, did you reference --

3 A I talked about it as the basis for -- for my
4 expert report in this -- in this case.

5 Q Is the CIR report, the final report, attached to
6 your expert report in this case?

7 A Yes, it was.

8 Q Does the CIR report that was attached to your
9 report in the case include the bullet points that are set
10 forth on the slide that the jury is viewing now?

11 A Yes, it did.

12 Q What was your view regarding the absence of
13 persuasive evidence that talc can migrate from the
14 perineum to the ovaries?

15 MR. SMITH: And again, your Honor, none of these
16 opinions are expressed in his report, in the four corners
17 of his report. I understand what the CIR did, but the
18 panel, he expressly said, did the review, not him. So I
19 object. This opinion about transmigration is not in his
20 report.

21 THE COURT: Overruled.

22 Q BY MR. WILLIAMS: Go ahead, Doctor.

23 A It was the sense of the panel that those
24 available data just simply did not reliably demonstrate
25 that talc could move from the outside of the body, at the
26 perineal area, inside the body and end up in the ovaries.
27 And, certainly, part of that was the panel's clear
28 acknowledgment that there's just no data on the first

1 step of that process, of talc going from the outside
2 getting into the vaginal cavity.

3 Q Let me ask you a separate question.

4 Was the conclusion of the expert panel that talc
5 is safe contingent on a finding that talc -- that talc
6 could not migrate, meaning did the panel conclude that
7 talc is safe but basing that on the notion that there's
8 no way that talc could get to the ovary?

9 MR. SMITH: Objection, your Honor. Hearsay. He
10 said he was not a voting member on the panel.

11 THE COURT: Sustained as phrased.

12 MR. SMITH: Thank you.

13 Q BY MR. WILLIAMS: Were you present for all of
14 the discussion regarding migration and all of the other
15 issues that are set forth on the board regarding talc?

16 A Yes, I was.

17 Q With respect in specific regard to this first
18 bullet point, the issue of whether or not talc can
19 migrate, did you listen to the discussion of the panel
20 members?

21 A Yes, I did.

22 Q Did you review the edits that they suggested to
23 the final report before the report was made final?

24 A Yes.

25 Q Was it your job to do that?

26 A That's -- yes.

27 Q Did you receive edits from members of the panel
28 in preparing the final report which included the bullet

1 points that are on the board right now?

2 A Yes.

3 Q With respect to the issue of migration, was the
4 conclusion of the panel that talc was safe contingent on
5 the notion that talc could not migrate?

6 A Um --

7 MR. SMITH: Your Honor, I'm going to object
8 again. It's hearsay.

9 THE COURT: Overruled.

10 THE WITNESS: The panel's finding was certainly
11 based on its understanding that it just isn't very likely
12 that talc moves from the outside in the perineal area up
13 to the ovaries.

14 Q BY MR. WILLIAMS: Let me refer you to the second
15 bullet here, which is "Lack of consistent statistically
16 significant positive associations across studies."

17 what are the types of studies that this bullet
18 point refers to?

19 A The CIR safety assessment included available
20 case-control epidemiology studies, cohort studies. They
21 looked at -- prospectively at large populations and
22 packaged all of that information together into a rather
23 large section presenting the epidemiology data.

24 Q What was the basis for the conclusion that there
25 was a lack of consistency regarding significant positive
26 associations across the study?

27 A It -- it wasn't hard. Some studies showed a
28 positive association between the use of talc and ovarian

1 cancer, and other studies said there isn't an association
2 between the use of talc and ovarian cancers.

3 The panel looked at that and said, there's a
4 lack of consistent positive association across studies.
5 Some do; some don't.

6 Q Let me direct your attention to the phrase
7 "statistical significance." Do you have that phrase in
8 mind?

9 A Yes.

10 Q With respect to the case-control studies that
11 were available to the panel at the time that you and
12 others drafted the CIR report, do you have any recall
13 regarding the relative number of studies that show a
14 statistically significant association and those that did
15 not have statistically significant findings?

16 A Yes. I think it's -- as we talked about this in
17 the panel meetings and at the -- I mean, it's all -- it
18 looks pretty obvious when you package it up. It's pretty
19 close to half and half.

20 Q What significance did that have, half
21 statistically significant and half -- half not
22 statistically significant and half of the studies being
23 statistically significant?

24 A For the panel, it loops back to that sentence at
25 the top ending with a colon. It calls in to question --

26 MR. SMITH: Your Honor, excuse me. I just want
27 to object. He's speaking on behalf of the panel. It's
28 clear hearsay.

1 THE COURT: Overruled.

2 MR. SMITH: Okay.

3 THE WITNESS: The lack of consistent
4 statistically significant positive associations was part
5 of what contributed to that view that maybe the
6 statistically significant associations aren't really
7 valid.

8 Q BY MR. WILLIAMS: You have significant
9 experience with epidemiological studies?

10 A Over my career at FDA and during my work at CIR,
11 regular consideration of epi studies.

12 Q When the results of a study are not
13 statistically significant, what is the significance of
14 that to you?

15 I don't mean to overuse the word, but what does
16 that mean to you?

17 A Well, it means that you haven't demonstrated
18 what you started out to demonstrate. In the case of a
19 study that looks at a possible link between the use of
20 talc and ovarian cancer, you haven't made the case that
21 these are linked, that there is an association.

22 Q Let me direct your attention to the third
23 bullet. The third bullet says, "Uniformly small risk
24 ratio estimates in studies reporting positive
25 associations."

26 Do you see that?

27 A Yes, I do.

28 Q Why the use of the phrase "small risk ratios"?

1 A Well, that, in all of our discussions, was the
2 way in which the available studies seemed to be best
3 characterized. These -- where there was a positive
4 association, it -- just for use of a number, it was in
5 the range of 1.3. And in the discussions, the panel
6 basically referred to that as a -- a small relative risk
7 or odds ratio, whichever way it was captured, a small
8 increase.

9 Q Let me direct your attention to the fourth
10 bullet. The fourth bullet says, "Failure to rule out
11 plausible alternative explanations of the statistically
12 significant results including biases, confounding risk
13 factors, and exposure misclassifications."

14 Please describe that section and that point.

15 A Well, as was talked about at all of the
16 discussions, this is the other shoe, if you will.

17 The previous bullet said that the -- when there
18 was a positive association, it just wasn't that big. But
19 when it's not that big, you really start to ask the
20 follow-up question: How could that be wrong? You know,
21 you accept that there's a positive association, it was
22 statistically significant, but it's not very big. Why
23 could that be wrong?

24 And what the panel -- I think epidemiology in
25 general looks at is what might the biases be in
26 collecting those data. Recall bias is a not-uncommon
27 bias to consider in looking at epidemiology data. How
28 well can you actually remember what happened 15 years

1 ago.

2 Q When a --

3 A During the discussion, there was also an
4 acknowledgment that there may be confounding risk
5 factors, other things going on, that might actually be in
6 play, and talc might not be the real association.

7 The panel repeatedly -- I mean the
8 discussions -- repeatedly acknowledged that in each of
9 these case-control studies, most of the women with
10 ovarian cancer had never used talc.

11 So something else other than talc has to be at
12 play here. So the idea that there would be confounding
13 risk factors was acknowledged, and then finally the
14 possibility of exposure misclassifications. I mean, it
15 could be as simple as was it talc or was it cornstarch?
16 Do I really remember?

17 And absent a sense of how good those
18 recollections are, it's possible to think that a small
19 statistically significant finding might actually go away
20 if you had better data.

21 Q Let me direct your attention to the fifth bullet
22 which says, "Absence of statistically significant
23 associations between ovarian cancer and using talc-dusted
24 diaphragms or condoms."

25 why was that significant?

26 A During the discussion, it was noted -- this
27 almost refers back to that first bullet -- but the panel
28 was thinking that, you know, if a partner uses a condom

1 that's talc-dusted or the woman herself uses a diaphragm
2 that's talc-dusted, what happens is that the talc is now
3 closer to the ovary. You don't have that question any
4 longer of does it get inside. It's already inside.

5 And the panel considered that, okay, that's good
6 to know. So the ability to get to the ovaries has to be
7 increased. I mean it's closer. And when those
8 circumstances didn't lead to an increase in ovarian
9 cancer, the panel and myself included thought that was
10 significant.

11 Q Let me direct your attention to the sixth bullet
12 point which says, "Overall lack of positive
13 exposure-effect relationships."

14 Does this refer to dose response?

15 A Yes, that's what we are trying to talk about,
16 the more exposure, the more effect.

17 I'm not sure I know how to amplify on this.
18 It's just the overall view of these positive
19 exposure-effect studies. Certainly not all of the
20 epidemiology studies provided -- excuse me -- provided
21 information on the extent of the exposure. Some were
22 just did you ever use talc or you never use talc? That
23 doesn't tell you much about the extent of exposure.

24 But some studies asked how frequently did you
25 use talc. Some studies asked over how many years did you
26 use talc. And those give you some handle on how much
27 exposure might have occurred. Unfortunately, none of the
28 studies asked how much talc do you use --

1 Q In terms of quantity --

2 A -- the third feature.

3 Q I'm sorry. I didn't mean to speak over you.

4 You said how much talc is used. Are you talking
5 there about the sheer quantity of talc that was applied?

6 A The magnitude, yeah.

7 Q Are there some studies that were reviewed and
8 available and cited in the report of the CIR that dealt
9 with both the frequency of a woman's use and the duration
10 or number of years of their use?

11 A Yes, there were some of those in the report.

12 Q Were those reviewed as well by the panel?

13 A Yes.

14 Q Let me direct your attention to the seventh
15 bullet. The seventh bullet reads: "Inverse trends for
16 both duration of use and frequency of use in some
17 studies."

18 what did that refer to?

19 A well, that's the -- again, the way we captured
20 this, this is the second shoe of the dose-response
21 discussion. When the data from a study that looked at
22 frequency of applications or duration, total duration of
23 use, when we looked at those -- I mean, I can't say every
24 place, but you would pick a study and look at it and find
25 a higher exposure, more frequent uses, longer duration of
26 use at a lower odds ratio than less frequency of use or
27 shorter total duration. And it just left us scratching
28 our heads.

1 Q why would the notion that longer use or more
2 frequent use having a lower risk ratio cause you and the
3 other panel members to -- and the others who worked on
4 the report to scratch your heads?

5 A It makes no sense.

6 Q Could you amplify?

7 A I'm sorry. Say again.

8 Q Could you amplify?

9 A In whatever probability you think might exist
10 for talc moving from the perineal area through the
11 vagina, past the cervix, through the uterus, up the
12 fallopian tubes, to get to the ovary, if there's more
13 stuff there to do that, then there ought to be more
14 consequence at the end of it, and a more frequent use in
15 concept ought to lead to more of the result. If you used
16 it over a lifetime, it ought to lead to more of the
17 result.

18 You know, again, unfortunately, the question of
19 how much you applied was just never legitimately captured
20 so that you can add that in. But then that now comes to
21 the surprise.

22 Wait a minute. If that should lead to more
23 consequence, it's less. It just doesn't fit a pattern of
24 what you would expect in a cause-effect relationship. It
25 just doesn't fit the pattern.

26 Q Let me direct your attention to the eighth
27 bullet point, which says, "Absence of a plausible
28 biological mechanism."

1 what was the focus of the discussion of the
2 panel members regarding biological mechanism?

3 A well, the focus was to turn the thinking around.
4 You know, just clearly the panel is not impressed with a
5 good bit of the data. That's clear from the bullet
6 points that they have given up to this point.

7 But what could possibly be going on with talc
8 that might actually suggest an ovarian cancer risk? How
9 biologically could that occur? what is it that talc
10 would do even if it did get to the ovaries?

11 So the panel really looked at that question.
12 You know, it didn't believe that it would easily get to
13 the ovaries, but they posed that question. Suppose it
14 did? what mechanism do we know about that could suggest
15 that?

16 And the -- the view of -- you know, I went
17 through the background of the panel members. I think it
18 adds up to well over 200 years of research experience in
19 cancer causation. They looked at it and said, there's no
20 plausible biological mechanism by which we think this
21 could happen.

22 Q Let me, if I could, for a moment, Doctor --
23 Could you put up the slide again? I believe it
24 was slide 3 which is the panel members.

25 I just wanted, for the sake of clarity,
26 Dr. Andersen, to have you point out the members of the
27 review panel who had those combined years of experience
28 in toxicology-type issues.

1 A Oh. It's Dan Liebler, Curt Klaassen, Tom Slaga,
2 and Ron Shank have all made their careers on researching
3 the question of cancer causation.

4 Q Let me ask you if there was any sort of
5 discussion -- if you could go back to the other slide,
6 which was the eighth bullet point there.

7 was there a discussion of what the studies that
8 were included in the reference materials said about tubal
9 ligation or whether there was any relationship or
10 association found in the studies where women had actually
11 had their tubes tied and any -- whether that affected an
12 association between talc use and ovarian cancer?

13 A Well, yes, that was part of the discussion.

14 The panel looked at that subset of epidemiology
15 studies that reported results in women who had undergone
16 a tubal ligation. And at least in concept, the -- the
17 temporal issue of when did they have it, when were they
18 exposed, put that aside for a moment, but tubal ligation
19 ought to prevent talc from getting to the ovaries.

20 And the panel looked then at those studies and
21 it was a mixed bag. Some of them in which this blockage
22 that should have prevented any exposure to the ovaries,
23 there was some data that suggested there was still a
24 positive association. It didn't make a lot of sense, but
25 it was what it was. But there were other studies that
26 showed that, when you blocked this, the odds ratios went
27 down.

28 Q What does that say -- the phenomenon that you

1 just described in the studies -- what does that say about
2 whether the risk ratios or odds ratios that were then
3 looked at could be viewed as establishing a causal
4 connection between the use of talc and ovarian cancer?

5 A Well, in the panel's discussion of how these
6 associations between exposure to talc and from the epi
7 studies might be linked to the endpoint of actual ovarian
8 cancer, to assert that talc causes it when a tubal
9 ligation has blocked the passage, seemed to call that
10 into serious question.

11 Q Let's turn to the final bullet. The final
12 bullet says, "Lack of credible defensible evidence of
13 carcinogenicity from the results of epidemiological
14 studies of occupational exposures and animal bioassays."

15 My question is this: Did the panel, the expert
16 panel, review animal studies that had been done in the
17 area of talc in connection with ovarian cancer?

18 A Yes, they did.

19 Q Did the panel review studies that dealt with
20 human -- strike that.

21 Did the panel review studies dealing with
22 subjecting human ovarian cells to talcum powder?

23 A Yes, those cell studies were included.

24 Q Describe for the jury the level of experience of
25 the people on the expert panel in reviewing animal
26 studies and human cell studies and carcinogenicity.

27 A Well, I gave you the figure of 200-plus years of
28 research experience in -- in looking at cancer causation.

1 You can add to that the 30 years of research experience
2 from Paul Snyder and the 20 years of research experience
3 from Ron Hill looking at cellular and animal studies.

4 Q Let me direct your attention to an animal study
5 that has been discussed a lot in this courtroom.
6 Specifically it's the NTP, National Toxicology Program,
7 rat inhalation -- it's actually rat and mice --
8 inhalation study from 1992.

9 Are you familiar with that study?

10 A Yes, I am.

11 Q I'll direct your attention in your book to
12 Exhibit L938.

13 A Yeah, these are in order. Yeah, there it is.
14 Okay.

15 Q This is the rather lengthy study relating to rat
16 inhalation; correct?

17 A Yes, it is.

18 Q Did the expert panel from CIR review that study
19 in its entirety?

20 A In depth.

21 Q Let me represent to you, Dr. Andersen, that one
22 of the experts called on behalf of Ms. Echeverria,
23 Dr. Plunkett, suggested that the rat inhalation study
24 from 1992 was a useful study to see the effects that talc
25 would have on the lungs of the rats at various points in
26 time.

27 Based upon the expert panel's review of that
28 study and comments on that study by other parties, what

1 can you tell the jury regarding the usefulness to the
2 panel of the rat inhalation study?

3 MR. SMITH: Your Honor, this is not mentioned in
4 his report, and he's not on the expert panel. I object.

5 THE COURT: I think the question as phrased is
6 inappropriate. It's sustained.

7 First of all, it's a narrative; and, secondly,
8 it's one thing to ask him what the panel concluded. It's
9 another thing to ask whether some of the panel found it
10 useful.

11 MR. WILLIAMS: I'll rephrase, your Honor.

12 Q BY MR. WILLIAMS: Did the expert panel review
13 this study?

14 A Yes, they did.

15 Q Was there a discussion of the study in the
16 report that is attached to your report?

17 A Yes, it was discussed in the CIR safety
18 assessment.

19 Q This study specifically?

20 A That's correct.

21 Q Was the discussion of the report that is
22 reflected in the CIR report that is attached to your
23 expert report in this case express the feelings of the
24 expert panel regarding this study?

25 A Yes, it did.

26 Q Were you present for the discussion of the rat
27 study when the CIR met on those occasions?

28 A Yes, I was.

1 Q All I'm asking is if you could describe the
2 impact, if any, of the rat inhalation study on the
3 conclusions of the panel.

4 MR. SMITH: Your Honor, that calls for
5 speculation.

6 THE COURT: Overruled.

7 THE WITNESS: The -- the panel discussion was
8 very clear that this study did not demonstrate a lung
9 toxicity for inhaled talc.

10 Q BY MR. WILLIAMS: why?

11 A Well, there were two primary reasons, both
12 highly technical, and then relating to how the study was
13 done. The first is the talc exposures that were actually
14 done were done by creating talc in really tiny particles.
15 And the panel I think acknowledged that nobody had a
16 choice but to do that because if they weren't really tiny
17 particles, they weren't going to get into the lungs of
18 the mice or rats. So there was a logic to why it was
19 done, the panel understood that.

20 But by doing that, the study created an
21 artificial exposure circumstance that, in the view of the
22 panel, just totally overloaded the lungs of the poor
23 animals. So that was the first point that the panel came
24 to.

25 The second point is -- is more nitpicky but
26 related to the conduct of animal studies. There were
27 periods during this lifetime exposure, a hundred and some
28 weeks these animals were treated to this insult, and in

1 different periods of time the exposure simply got out of
2 control. It -- in one case it skyrocketed for seven
3 weeks to well above the level that in parlance of people
4 who do these animal studies call the maximum tolerated
5 dose.

6 And, as a rule, when certainly Paul Snyder
7 jumped in on it in terms of his veterinary pathology
8 expertise, but in general, it's pretty understood, when
9 you exceed the maximum tolerated dose, the effects that
10 you see are not necessarily related to the agent in
11 question. They relate to having exceeded this dose.

12 So interpreting the findings, which were one of
13 the two species and one of the two sexes had some
14 evidence of cancer, what the panel said is, we can't
15 trust that. First of all, the exposures were massive. I
16 think -- I'm not sure it was ever captured in the
17 transcript, but the notes I recall seeing said you could
18 have done this with dust bunnies and gotten the same
19 result. This doesn't tell you about talc. It tells you
20 about overloading the ability of the mice and rats to
21 really process this kind of insult.

22 So those were the two factors that the folks who
23 conducted the study acknowledged that this existed. They
24 just concluded that you can still rely on the findings.

25 Q Let me stop you there for a moment.

26 The criticism -- that's my word. Strike that.

27 The view that you just expressed of the NTP rat
28 study that the panel had that we just can't trust -- that

1 was the words you used -- was that view consistent with
2 reference materials that are included in the CIR report
3 regarding what other bodies thought about the NTP rat
4 study?

5 A Yes.

6 Q Let me refer you to the exhibit that you've had
7 in front of you, Exhibit L384, which is the final final
8 report that was published in the journal. Do you have
9 that in front of you? Again, it's L384.

10 A Yes.

11 Q Let me direct your attention to page 58 of
12 Exhibit L384. Is that one of the pages where the
13 references are listed?

14 A That's correct.

15 Q And that's the 218 references you mentioned
16 earlier today?

17 A That's correct.

18 Q Let me direct your attention to reference number
19 11 on page 58. Do you see that?

20 A Yes, I do.

21 Q And does that refer to one of the -- strike
22 that.

23 Does that refer to the proceedings of the
24 Bethesda, Maryland, workshop relating to consumer uses
25 and health perspectives on talc?

26 A Yes.

27 Q Was that one of the references that was reviewed
28 by the panel?

1 A Yes, it was.

2 Q Was the view that you just expressed, the view
3 of the nine members of the panel that you described,
4 consistent or inconsistent with the views of the NTP talc
5 study set forth in Reference Number 11 to the report?

6 A Yes, it was.

7 Q One of the studies about which there's been
8 discussion is a study called Hamilton. Are you familiar
9 with the Hamilton study that was done relating to
10 injecting rats into the ovaries -- strike that --
11 injecting talc into the bursa of rat ovaries?

12 A Yes, that's part of the safety assessment of
13 which I'm an author.

14 Q Is that referenced in the references for the
15 final report of CIR?

16 A Yes, it is.

17 Q And, again, this is Hamilton 1984?

18 A I believe that's the date. I'm...

19 Q I'd ask you to comment on the notion -- strike
20 that.

21 Are you familiar with the difference between a
22 chronic exposure and an acute exposure to a substance?

23 A Yes, that's part of how we organize our reports.

24 Q Is that dichotomy, chronic on the one hand and
25 acute on the other, something that you consider when
26 reviewing the safety of ingredients?

27 A Yes, it is.

28 Q You're familiar with the Hamilton study?

1 A I am.

2 Q Can you describe or do you recall the
3 methodology of the Hamilton study; that is, how talc was
4 introduced to the rats?

5 A Yes, I do.

6 Q Please describe.

7 A It's not a particularly pleasant experiment.

8 The rats were anesthetized and their abdomens
9 were opened and the ovaries were pulled out external to
10 the body. It was mentioned that the ovary that's
11 actually in the rat contained an inside and outside sac.
12 And that was truly the case.

13 What the researchers then did was they injected
14 a bolus amount of talc under that outside sac so it
15 didn't have to go through the sac, it went under it,
16 right onto the surface of the ovaries.

17 After they did that, they put the ovaries back
18 in the animal, sewed them up, and put them back in the
19 cage.

20 And as a function of time, after that, they
21 looked -- well, sacrificed is the word. They killed the
22 animals and looked at what changes had happened in the
23 ovaries. They look at two weeks, look at four weeks,
24 look at six weeks as a function of time and see what
25 happened as a result of the exposure to talc. And that's
26 what the study was.

27 Q And just getting to the point of it, did the
28 study show that there was an increased toxicity over time

1 based upon the exposure of those ovaries to the talc?

2 A Boy, I really don't like the word "toxicity."
3 what the study found --

4 Q Use the word that is appropriate. I'm sorry.

5 A -- was two things. They reported that the
6 ovaries were cystic. Cysts had formed on the surface of
7 the ovaries. The other thing they reported -- and that
8 wasn't all of the ovaries, just in some of the ovaries
9 they reported that.

10 They also found what they called papillary
11 changes in the surface of the ovary, and that was four
12 out of the ten -- four of ten animals. And that's what
13 they reported. So those were the findings.

14 Q Based upon your review of the Hamilton study,
15 was the type of exposure of the ovaries to talc, based on
16 the methodology there, an acute exposure? chronic
17 exposure? where in that dichotomy would you express it?

18 A I think it defies an easy categorization because
19 the impact of how they did the study was to create a
20 chronic exposure to the ovary.

21 Q How so?

22 A Remember talking about that bursa, it is a
23 barrier to stuff getting past it into the ovary? It's
24 also a barrier to stuff getting out. So now you have
25 that talc that was put into that space between that sac
26 and the ovary and now it's sitting there, day after day
27 after day.

28 So as I look at it, again, it doesn't fit the

1 normal mode of a chronic study. Normally a chronic study
2 is that you just keep adding more stuff, more stuff.
3 That's done because classically, whether it's animal or
4 human, you have to add more because they get rid of it.
5 So to keep it going, you have to add more.

6 In this case, it just sat there and exposed the
7 ovary continuously. That is as close to chronic as I can
8 think of.

9 Q With respect to the Hamilton study, were the
10 changes, if any, to the ovarian cells cancerous?

11 A The authors I think specifically noted that they
12 found no cancer in the ovaries.

13 Q And did that -- strike that.

14 Was that the finding throughout the lifetime of
15 the rats even if it was a rat that was sacrificed near
16 the end of its life?

17 A I don't -- I would have to go look at the study
18 to remember whether any really reached end of life. But
19 as long as the study went on, none of the animals
20 developed any cancers.

21 *[4:47 P.M.]*

22 MR. WILLIAMS: Your Honor, I was going to shift
23 to another study. Is this an appropriate time?

24 THE COURT: I would think so. All right. Let
25 me ask counsel a question, and then I will query the
26 jury.

27 Do you have matters to take up in the morning?

28 MR. WILLIAMS: Could I have one moment to ask,

1 your Honor?

2 THE COURT: Sure.

3 (A discussion is held off the record.)

4 MR. WILLIAMS: Your Honor, I think the answer is
5 yes, there is one matter we'd like to take up today, if
6 we could. But I do think in the morning we've got one or
7 two shorter matters to raise. So the answer is yes.

8 THE COURT: So the answer is yes. So should we
9 ask the jury to be here at 9:30? would that be better?

10 MR. WILLIAMS: That would be fine.

11 THE COURT: All right. So 9:30, folks,
12 downstairs. Thank you very much. Have a good evening.

13 Leave your notes. Do not discuss the case. Do
14 not do any research. Do not form your opinions until you
15 get into the jury room and have the opportunity to talk
16 to each other.

17 (Jurors excused.)

18 THE COURT: You are welcome to step down,
19 Doctor.

20 (THE FOLLOWING PROCEEDINGS WERE HELD IN OPEN
21 COURT OUTSIDE THE PRESENCE OF THE JURY:)

22 MR. WILLIAMS: Dr. Andersen, you can step out in
23 the hall.

24 (Dr. Andersen excused from the courtroom.)

25 THE COURT: Okay. Standing or sitting, as you
26 wish. I know everybody has been sitting for a while.

27 MR. SMITH: You don't mind if we stand?

28 THE COURT: I do not mind if you stand, and I

1 might do the same in a bit.

2 MR. WILLIAMS: Thank you, your Honor.

3 At this time, given that the plaintiff has
4 closed, the defense moves for a nonsuit. And we are
5 prepared to file a memorandum today. Permit me, if you
6 would, to state the basis for the nonsuit.

7 We seek judgment of nonsuit on the ground that
8 the plaintiff has failed to introduce evidence sufficient
9 to carry her burden of proof, and the allegations fail as
10 a matter of law on the following issues:

11 A. That defendants had a duty to warn;

12 B. That the defendants' alleged failure to warn
13 was a substantial factor in causing plaintiff's harm;

14 C. That defendants engaged in conspiracy or
15 could be liable for public advocacy;

16 D. That the defendants can be liable for
17 negligence per se, based on FDA regulations or for fraud
18 on the FDA;

19 E. That defendants can be liable on the basis
20 of general negligence independent from plaintiff's claim
21 for negligent failure to warn.

22 That's the first motion that will be filed.

23 The second motion is a partial nonsuit as to
24 punitive damages. The basis for that -- and in the
25 alternative, to the relief requested above, the
26 defendants seek partial nonsuit pursuant to Section
27 581(c) subsection (b) on the issue of liability for
28 punitive damages.

1 Finally, the third motion is partial nonsuit as
2 to defendant Johnson & Johnson, the parent company. We
3 believe that partial nonsuit pursuant to Section 581(c)
4 subsection (b) should be granted as to defendant J&J on
5 the ground that J&J cannot be liable for the alleged
6 conduct of its subsidiary, JJCI. And plaintiff has not
7 submitted sufficient evidence on which the parent company
8 could be liable.

9 We have the papers to be filed today. We would
10 ask that we set a hearing for this on, say, Monday --
11 Monday morning, if that would be appropriate for the
12 Court.

13 And I believe that is all I needed to say at
14 this point.

15 THE COURT: Mr. Robinson?

16 MR. ROBINSON: I think we're going to have
17 Mr. Wilson just talk briefly. And if there's going to be
18 a --

19 THE COURT: Sure.

20 Mr. Wilson?

21 MR. ROBINSON: If there's going to be a brief,
22 we will wait for the brief.

23 THE COURT: I'm assuming you would like to file
24 a brief.

25 MR. WILSON: We can, your Honor, but we will do
26 whatever the Court would prefer. We could argue it
27 orally if the Court would prefer that right now as well.

28 MR. WILLIAMS: We'd prefer that counsel and the

1 court read the briefs.

2 THE COURT: Well, I can't read the briefs today.
3 So if you would prefer to file a written brief, we could
4 do that. And you tell me when you'd like to do that. If
5 counsel wants to argue this on Monday, I'm thinking maybe
6 you ought to file your brief by Monday. And then we
7 could argue this on Tuesday morning.

8 That would be better, I think, because counsel,
9 I presume, has spent more than the last five minutes
10 writing the motion. And you'd probably like more than
11 tomorrow close of business to file your written response.

12 MR. WILSON: Mr. Webb and I were in the hallway
13 during the examination of Dr. Andersen. And I saw two
14 bankers boxes come in with that motion for nonsuit. I
15 know, traditionally, I believe a motion for nonsuit or
16 opposition has a 15-page limit. I don't know if the
17 Court is -- wants page limits here. I don't know what is
18 the specificity.

19 THE COURT: I haven't seen the motion, but I
20 hope it doesn't exceed the 15-page limit.

21 MR. WILLIAMS: I personally don't know whether
22 any of the three -- the three different motions --

23 THE COURT: And it might have the exhibits
24 attached to it.

25 MR. WILSON: I saw two bankers boxes and I got a
26 little bit scared.

27 MR. WILLIAMS: If they do exceed, then we would
28 be happy to file -- one of them does, your Honor. And so

1 we would seek leave to file beyond the limit.

2 THE COURT: Mr. Webb, how long is the motion?

3 MR. WEBB: I believe, your Honor -- and I have
4 been here this afternoon, so I haven't seen the final
5 draft, but I believe it's approximately 30 pages.

6 THE COURT: Okay.

7 MR. WEBB: But I would add, your Honor, that
8 most of that particular brief would be familiar to all
9 counsel involved because it addresses, in part -- it
10 addresses two things: one, the failure to demonstrate
11 a duty to warn; and, two, the causation issues that are
12 extremely familiar to all counsel involved in the case.

13 So I don't think the issues presented will be
14 drastically different than what counsel should already be
15 aware of.

16 THE COURT: Does the plaintiff want 30 pages?

17 MR. WILSON: Your Honor, it sounds like there's
18 actually three motions, one of which is 30 pages. And it
19 sounds as if the others are 15. So I think we're talking
20 more about maybe 60 pages. I don't know that we want to
21 try and compete on that level with page limits, but
22 whatever the Court prefers.

23 THE COURT: If you want to file a written brief,
24 you're invited to do that and file it by Monday. If you
25 want to take 30 pages, that's fine. If you don't, that's
26 okay too.

27 MR. ROBINSON: Your Honor, the question, at
28 least I have, is the 30 pages for the three briefs?

1 MR. WEBB: No, there's one that's approximately
2 30 pages, and then the other two, I believe, are less
3 than 10 pages each. They are much shorter, the punitives
4 and the Johnson & Johnson corporate structure briefs.

5 THE COURT: So it's entirely up to plaintiff's
6 counsel how you'd like to proceed in terms of briefing.
7 I will certainly give you leave to file a longer brief.

8 MR. WILSON: One concern that I have -- and, you
9 know, we've all kind of been thinking about jury
10 instructions and verdict form -- early on, we made a
11 request for the CACI 418 instruction based on negligence
12 per se, with the statute or regulation being 21 CFR
13 740.1(a), with then the language in CACI 418 that says
14 the plaintiff still has to prove causation, causation
15 being defined by what the Court has already identified,
16 CACI 430, or maybe it was 431 or 435, modified a bit.

17 Part of the concern that I personally have in
18 opposing a nonsuit at this point in time is I don't know
19 if that instruction is going to be given. And so,
20 therefore, I don't even know what claims are on the
21 table.

22 Usually, jury instructions like this are kind of
23 hammered out before this point in time. So I think it
24 might be helpful if we addressed jury instructions so we
25 could fairly oppose this motion to know what claims are
26 out there. For example, the CACI 400, general negligence
27 claim, or if it was going to be a CACI 1220 general
28 negligence claim, the 418 claim, as well as the 1222

1 failure to warn claim.

2 THE COURT: Mr. Williams?

3 MR. WILLIAMS: That might make sense, your
4 Honor. We put the 318 -- because, of course, we don't
5 know for certain what the Court's pleasure is going to be
6 on the negligence per se instruction. That's why the
7 brief treats that issue separately.

8 MR. WEBB: Yes, your Honor. And, you know, the
9 proposition that you have to have a finalized set of jury
10 instructions before you can argue or brief a nonsuit
11 motion, I don't think is actually accurate given that the
12 nonsuit always comes at the close of the plaintiff's
13 evidence.

14 And typically the jury instructions aren't
15 finalized until final charging conference just before
16 closing. So as Mr. Williams alluded to, what we
17 attempted to do in the longer of the briefs that
18 addresses the duty and the causation issues is to
19 address -- and part of the link, frankly, is to address
20 specifically the different arguments and causes of action
21 that plaintiffs have suggested are still in the case.

22 And we, of course, take the position that
23 they've failed to present evidence to permit those causes
24 of action to be in the case, if they were even ever
25 properly in the case to begin with.

26 So that really is the thrust of the longer of
27 the three motions.

28 THE COURT: So let me suggest the following:

1 Before we finalize what we're going to do here, why don't
2 we recess for the afternoon and give plaintiff's counsel
3 an opportunity to read the brief, and then I'd like to
4 read it as well. And then I think in the morning we
5 would have a better sense of how we should address this
6 because then you'll have had time to read it.

7 MR. WILSON: Thank you, your Honor.

8 MR. WILLIAMS: Thank you, your Honor.

9 MR. WEBB: Thank you, your Honor.

10 THE COURT: I think that's what we should do.
11 Did you leave a copy of the brief with the clerk?

12 MR. WEBB: We are filing it right now, your
13 Honor.

14 MS. ZUKIN: Has it been served?

15 MR. WEBB: He's serving it on you right now.

16 THE COURT: Is it on Case Anywhere? Is it on
17 Case Anywhere?

18 MR. WEBB: It will be, your Honor, as soon as we
19 have it filed. But we're prepared to serve it on Case
20 Anywhere right now. But we have courtesy copies here for
21 plaintiff's counsel as well.

22 THE COURT: All right. So I think we should
23 take this up in the morning.

24 MR. ROBINSON: What time, your Honor?

25 THE COURT: Why don't you be here at 8:30, and
26 we'll talk about how to do it. And you said there were a
27 couple of other things you wanted to take up?

28 MR. WILLIAMS: There are. One relates to, I

1 believe, witness Felix. There's a motion. There was a
2 motion in limine filed relating to Dr. Felix, so we'd
3 like to take that up if we could. That's of the shorter
4 variety, I think.

5 MR. CACHAN: It's two pages or three pages, or
6 something.

7 THE COURT: When was that filed?

8 MR. CACHAN: This afternoon, your Honor.

9 THE COURT: Oh, okay.

10 MR. WILLIAMS: It has to do with whether certain
11 things can be delved into on cross-examination, and, if
12 so, how much.

13 THE COURT: And do you have anything else to
14 take up in the morning?

15 MR. WILSON: I don't think so.

16 MR. CACHAN: We can take that up at the noon
17 hour, actually, tomorrow.

18 MR. SMITH: I think we're okay.

19 MR. ROBINSON: Thank you, your Honor.

20 THE COURT: Okay. See everybody at 8:30.

21 (Whereupon an evening adjournment was taken at
22 4:40 P.M. with the matter to be resumed at
23 8:30 A.M. on August 11, 2017.)
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SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,
SPECIAL TITLE (RULE 3.55)

JOHNSON & JOHNSON TALCUM
POWDER CASES.

JCCP NO. 4872

REPORTER'S CERTIFICATE

I, CAROLYN GREGOR, CSR 2351, pro tem reporter of
the Superior Court of the State of California, for the
County of Los Angeles, do hereby certify that the
foregoing pages, 3103-3204, comprise a full, true and
correct transcript of the proceedings and testimony taken
in the above-entitled cause on August 10, 2017.

Dated this 10th day of August, 2017.

CAROLYN GREGOR, CSR 2351
OFFICIAL PRO TEMPORE REPORTER

Exhibit 134

August 11, 2017

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

COORDINATION PROCEEDING,)
SPECIAL TITLE (RULE 3.55))
) JCCP NO. 4872
)
JOHNSON & JOHNSON TALCUM)
POWDER CASES,)
_____)

MORNING SESSION
REPORTER'S DAILY TRANSCRIPT OF PROCEEDINGS
AUGUST 11, 2017

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August 11, 2017

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August 11, 2017

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August 11, 2017

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1 CASE NUMBER: JCCP 4872
2 CASE NAME: JOHNSON & JOHNSON
3 TALCUM POWDER CASES
4 LOS ANGELES, CALIFORNIA AUGUST 11, 2017
5 DEPARTMENT 307 HON. MAREN E. NELSON
6 APPEARANCES: (AS HERETOFORE NOTED.)
7 REPORTER: PAMELA COTTEN,
8 CSR NO. 4497
9 TIME: 8:48 A.M.

10 MORNING SESSION

11 (The following proceedings were
12 held outside the presence of the jury:)

13 THE COURT: Good morning, all.

14 MR. WILLIAMS: Good morning, your Honor.

15 MR. ROBINSON: Good morning, your Honor.

16 THE COURT: Good morning.

17 ALL: Good morning, your Honor.

18 THE COURT: On the record outside the presence
19 of the jury. All trial counsel present. Have a seat,
20 folks.

21 On the motion in limine, I read the motion, I
22 read the opposition regarding Dr. Felix. I'm not
23 inclined to grant the motion, but I am a little concerned
24 that we are going to have a long detour into lung cancer,
25 which we don't need to have.

26 MR. ROBINSON: No. It will be very quick, your
27 Honor. We're not going to do that.

28 THE COURT: So let me hear from Mr. Williams and

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1 Mr. Robinson.

2 MR. WILLIAMS: Well, actually, it was Mr. Cachan
3 who was going to do it, your Honor, and he is not here
4 this morning. But we just wanted to avoid that detour
5 that the Court is referencing and try to keep that away
6 from the jury because it's not as important what the
7 matters were about as it is the amount of money that he
8 was paid and that type of thing by our client.

9 So to the extent that there are just certain
10 industries that, if you start jumping there, that's
11 unduly prejudicial, in our view. And so the issue should
12 be related to this case, we think, in the first instance,
13 money is paid by our client, that type of thing.

14 MR. ROBINSON: Your Honor, when these experts
15 choose to work on a case, that's a part of their
16 background and that's -- look what they brought out with
17 Dr. Plunkett, three million dollars, I mean. So that's
18 what they've done. They have an expert who that's what
19 he's worked on before, and it's fair game. We're not
20 going to go on and drag it out. We're just going to
21 bring that point out, your Honor.

22 MR. WILLIAMS: With respect to Dr. Plunkett, you
23 will recall, your Honor, it was the total amount of
24 money. We didn't go into cell phone, using insects to
25 determine whether there's brain activity damage, and that
26 type of thing, and all of the specific opinions that she
27 has given in other cases. We didn't talk about the types
28 of other cases. What we talked about was money.

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1 MR. ROBINSON: They talked about plaintiff
2 lawyers and plaintiffs' cases, your Honor.

3 The important thing is this, is that this is
4 what Dr. --

5 MR. WILLIAMS: Felix.

6 THE COURT: Felix.

7 MR. ROBINSON: What he chose to work on. He has
8 worked on those cases.

9 THE COURT: I don't have a problem with that,
10 but I am concerned that if we are going to start getting
11 into what his opinions were in other cases --

12 MR. ROBINSON: No.

13 MR. SMITH: No.

14 THE COURT: -- then we're going to be down a
15 long detour about cancer that we don't need to go down.

16 MR. ROBINSON: We're not, your Honor.

17 MR. WILLIAMS: And let me be clear, your Honor.
18 Plaintiff/defense, that's absolutely fair game. The
19 ratio of plaintiff to defense, absolutely. But to talk
20 about -- to bring up tobacco and say that you've done
21 stuff in tobacco and to say that you've done stuff on
22 asbestos cases, we just think that that's inappropriate.

23 MR. ROBINSON: We've agreed no asbestos, but we
24 are not going to agree to other cases, your Honor.

25 THE COURT: I'm not going to grant the motion,
26 but I am going to ask plaintiff's counsel to be mindful
27 about not going down the road of what opinions did he
28 give, why did he give it. Otherwise we are going to be

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1 in mini trials on these other cases because we will be
2 hearing all about them.

3 MR. SMITH: Yes, your Honor.

4 THE COURT: I know where this will go.

5 MR. SMITH: Yes, your Honor.

6 THE COURT: All right. On the subject of the
7 motion for nonsuit, what does the plaintiff want to do in
8 terms of a schedule?

9 MR. ROBINSON: Your Honor, I did -- Scot, you
10 want to talk?

11 MR. WILSON: Your Honor, the motions are not as
12 lengthy as maybe we thought. I think one is about 30
13 pages, the others are about five and six.

14 If the Court wants written-out positions, we can
15 submit those. We would prefer to submit those as soon as
16 possible and have the motions argued as soon as possible,
17 but it is totally up to the Court's schedule.

18 THE COURT: If you can file written oppositions
19 today, I'll rule on them on Monday. That would probably
20 be the simplest thing to do.

21 MR. WILSON: I think we can do that, your Honor.
22 Obviously -- the one concern that I have, usually as
23 plaintiffs' lawyers, we get sometimes an oral motion for
24 nonsuit; sometimes we get a motion in writing. Typically
25 we don't do a written opposition.

26 THE COURT: You're not required to. I'm just
27 saying if you want to do one --

28 MR. WILSON: We will do one. The only concern

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1 that I have -- I mean, obviously, I think a lot of time
2 and effort went into citing the record. We will do our
3 best to provide citations with the understanding that,
4 given the very short time frame, we are not citing every
5 little bit and piece of testimony, but we will try our
6 best.

7 THE COURT: All right.

8 MR. ROBINSON: Your Honor, can we have until
9 Saturday? I do think that Mr. Wilson is here today --

10 THE COURT: You can have until Saturday.

11 MR. WILSON: Thank you, your Honor.

12 MR. ROBINSON: Thank you.

13 THE COURT: Just put it up on Case Anywhere so I
14 know that it's there. And it doesn't -- it doesn't need
15 to be elaborate. The law is very straightforward on this
16 issue. We needn't brief the law much. But if you want
17 to cite to certain evidence you think is important for
18 the Court to consider, that's what you need to do. And
19 you can do that in writing or orally. But I'll hear this
20 motion on Monday.

21 MR. WILSON: Thank you, your Honor.

22 MS. ZUKIN: Your Honor, we do have an issue
23 regarding exhibits and objections to our exhibits that we
24 thought were going to be coming in. So we just want to
25 know when to carve out time to deal with that.

26 THE COURT: What are -- we can do that right
27 now.

28 MS. ZUKIN: Mr. Wilson is ready.

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1 MR. WILSON: So we had a very productive
2 discussion with Mr. Webb yesterday. There's basically
3 four categories -- Jeff, do you mind putting up on the
4 screen --

5 THE COURT: Mr. Webb, is this your issue?
6 Because if so, please come forward.

7 MR. WILSON: For all the days and all the
8 different stipulations for each day, at this point we
9 have basically four categories of remaining items that I
10 don't even want to say are disputed but are areas where
11 we do need the Court to weigh in.

12 One relates to the photographs and images of the
13 talc in the tissue that Dr. Godleski took. We think
14 because a sufficient foundation was laid that he actually
15 took those photographs, looking at them himself on the
16 microscope, that those should be admitted, not just
17 identified.

18 We agree -- everybody agrees, nobody wants the
19 Court to take custody of the actual physical bottles, but
20 the photos of the bottles of talc, both Johnson & Johnson
21 as well as the bottles that we took -- that we showed
22 that have a warning as well as the bottles that Johnson &
23 Johnson introduced that do not have a warning, that the
24 photos of the bottles should be admitted, not just
25 identified.

26 There's an issue regarding certain scientific
27 papers and websites. For example, the Pycnogenol Horphag
28 Research advertisement, the NCI websites, all these

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1 different websites, we previously talked about how those
2 under 721(b) would be identified but not admitted.
3 Defendants' counsel would like some of those to be
4 admitted, ironically, taking the position because they
5 are just websites and not scientific publications. We
6 think those should be identified only.

7 Finally, there are specific portions of the
8 trial transcript where counsel read testimony from the
9 deposition for purposes of impeachment that they want to
10 have admitted. Traditionally, your Honor, I think
11 there's a rule on point, but no portion of the transcript
12 goes back to the jury. It is to be read back upon
13 request only.

14 So those are the categories basically, and they
15 can be identified later in specificity.

16 MR. WILLIAMS: Thank you, your Honor. I'm going
17 to handle this one.

18 THE COURT: Okay.

19 MR. WILLIAMS: With respect to the first
20 category on Dr. Godleski, I mentioned this yesterday.
21 Our position is that those are demonstrative exhibits.
22 They are the images that we used during his direct
23 examination of Dr. Godleski. He was asked by both sides
24 about it.

25 Our view is they are not exhibits that should be
26 admitted and, therefore, that should go back to the jury.
27 They are used for demonstrative purposes.

28 THE COURT: But they are a part and parcel of

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1 his report; correct?

2 MR. ROBINSON: Yes, your Honor.

3 MS. ZUKIN: Yes, your Honor.

4 MR. WILLIAMS: Oh, yes, absolutely. But there
5 are a lot of things that -- the reports don't go back,
6 the reports themselves are hearsay, the photographs are
7 hearsay. They are demonstratives that are used for the
8 benefit of the jury.

9 THE COURT: Well, the photographs actually I
10 don't think are hearsay. The -- I mean, they are like
11 any other photograph. If you lay a sufficient foundation
12 to admit them, they can come in. They are no different
13 than the photos of Ms. Echeverria or lots of other
14 photographs that have been admitted in millions of other
15 cases. The only -- they are just not hearsay.

16 So the question is, are they -- if we are not
17 admitting the report, should we admit the photos anyway?

18 MR. WILLIAMS: That's what we think the issue
19 is, your Honor.

20 MR. WILSON: On that point, your Honor, we agree
21 that the report doesn't go back, the report in its total,
22 but these were Exhibits 39A, B, and C. They were
23 segregated from the report, and it was made clear in the
24 testimony that these were photos that he took. It's a
25 lot like an image of an x-ray.

26 THE COURT: Right.

27 MR. WILSON: So I think a sufficient foundation
28 was laid.

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1 MR. WILLIAMS: Then at a minimum, your Honor, we
2 believe that the headings that were used when
3 Dr. Godleski was on there should be taken off.

4 MR. ROBINSON: We agree, your Honor.

5 MR. SMITH: We agree.

6 MR. WILLIAMS: The arrows that were pointed out
7 that were embedded in the photograph.

8 THE COURT: Let me stop you a minute. Do you
9 have clean copies of them without the arrows?

10 MR. ROBINSON: Your Honor, the arrows were -- he
11 was in deposition, and Mr. Klatt asked him to identify
12 the macrophages with arrows. And the arrows -- is that
13 what you --

14 THE COURT: That's what we are talking about.

15 MR. ROBINSON: No, those arrows were actually
16 done under sworn testimony, under oath, where he was
17 marking where, in his opinion, there was macrophages.

18 THE COURT: That's the demonstrative part of it.

19 MR. WILLIAMS: Right. That's not in the report.

20 THE COURT: So if you have clean copies, they
21 are the ones that come right out of his --

22 MR. ROBINSON: His report.

23 THE COURT: -- his report, that would be fine.

24 MR. ROBINSON: Could we use, obviously, the
25 arrows in final argument --

26 THE COURT: You can use the arrows in final
27 argument, sure.

28 MR. WILLIAMS: No objection to that, your Honor.

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1 On the second category, we have no objection to
2 the photographs of the bottles for both sides coming into
3 evidence.

4 THE COURT: Okay.

5 MR. WILLIAMS: On the third issue on -- there's
6 a distinction between scientific papers and certain
7 websites. With respect to the scientific papers, those
8 can be used for demonstrative purposes. We believe they
9 should be --

10 THE COURT: Hang on a second.

11 MR. WILLIAMS: -- potentially used in closing
12 argument as demonstratives, but that the scientific
13 reports should not come in.

14 But there's a difference between that and
15 certain of the websites. The websites that we argue
16 should come into evidence are the ones relating to
17 governmental websites as to which the Court can take
18 judicial notice. And we can provide briefing on that,
19 your Honor, if there's any issue.

20 But with respect to, for example, the NCI
21 website or Center for Disease Control website, the case
22 law is fairly clear on that -- and, again, we can provide
23 that to the Court -- that those matters are things as to
24 which the Court may take judicial notice of the content
25 of those sites.

26 That's very different from the Pycnogenol
27 website. We would not seek to have the Pycnogenol
28 website admitted into evidence. That was a demonstrative

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1 used through Dr. Plunkett to make a point. That's a
2 different thing.

3 So there's a difference between scientific
4 papers, certain governmental websites as to which
5 foundation can be laid, and the Pycnogenol ad. The ad
6 and the scientific papers themselves should not come in.
7 The website shouldn't come in.

8 MR. SMITH: Your Honor, we have clearly
9 established that the NCI website was not an official
10 statement, the NCI or the National Institutes of Health.
11 It was by those whatever, six, seven, eight people
12 independent. So it's not -- you can't take judicial
13 notice of something that's not an official statement by
14 the NCI.

15 THE COURT: So first of all, the scientific
16 papers do not come into evidence. 721(b)(3), the last
17 paragraph, is clear on this. If admitted, relevant
18 portions of the publication may be read into evidence but
19 may not be received as exhibits.

20 MR. SMITH: Sure.

21 MR. WILLIAMS: We are not seeking that, your
22 Honor.

23 THE COURT: All right. That's number one.

24 On the websites, if they are governmental
25 websites, FDA, for example, the Court can probably take
26 judicial notice of it. But I agree with counsel for the
27 plaintiff, the CIR is not a governmental website.

28 MR. WILLIAMS: Oh, no. CIR, we are not claiming

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1 that that -- I thought we were just talking about the NCI
2 website, actually, which is a different website.

3 THE COURT: Well, NCI -- the NCI website -- NCI
4 is part of DHHS.

5 MR. SMITH: And the National Institutes of
6 Health.

7 THE COURT: Right. I think the Court can take
8 judicial notice of the website. The fact that it says
9 that the -- I can't remember exactly what the language
10 is, but it's part of a governmental website.

11 MR. ROBINSON: Your Honor, can Mr. Wilson --

12 THE COURT: I appreciate there's a disclaimer of
13 some part of it, but it's part of a governmental website.

14 MR. WILSON: Very briefly, your Honor.

15 With respect to judicial notice, if we look at
16 Evidence Code 452(h), with something like this, we are
17 talking about judicial notice that is permissive.

18 And here with respect to a website, albeit a
19 governmental one, judicial notice to the extent it's
20 appropriate would be as to the existence of the document
21 but not for purpose of its truth.

22 And with respect to the existence, that gets
23 over an authentication hurdle; it doesn't get over the
24 hearsay hurdle. The document was used totally only as
25 cross-examination. It's clearly hearsay. The witness
26 never authenticated it, never established.

27 It was cross-examined. The vehicle for --
28 pursuant to which cross-examination was permitted was the

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1 witness was asked, like, you would agree that something
2 on the NCI website was a reliable authority. So it was
3 clearly trying to be invoked pursuant to 721(b).

4 To now say, well, this is different than 721(b),
5 after the witness is only cross-examined on the document
6 under 721(b), is unfair.

7 I think judicial notice is fine as to the
8 existence but not for purposes of truth. It should not
9 be an admitted exhibit.

10 THE COURT: That's probably right. Let me hear
11 from you.

12 MR. WILLIAMS: Two different issues, your Honor.

13 721(b) is for purposes of putting it in front of
14 that particular witness trying to establish foundation
15 that the document could be discussed with that individual
16 witness. It's a totally different analysis than whether
17 or not the court may take judicial notice of the
18 document.

19 We respectfully request the ability to brief it
20 because there are cases directly on point for websites
21 almost identical to this. And so it's two different
22 things.

23 THE COURT: I think the question, though, is
24 this: The Court can take judicial notice of the fact of
25 the website. The question is whether the Court can take
26 judicial notice of the statements in the website.

27 This is much like we are regularly asked to take
28 judicial notice of court files. We can take judicial

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1 notice of the pleading but not of the facts that are
2 stated in the pleading.

3 MR. WILLIAMS: If I may, your Honor. Here is
4 the legal distinction, as I understand it, from the cases
5 we saw. You are quite correct that the statements
6 contained on the website do not come in for the truth of
7 those statements that, in fact, there's inadequate
8 evidence related to talc. No, that's not what it is.

9 But the fact that that governmental website says
10 that, that has meaning in this case. It has meaning in
11 terms of the state of mind of our client, it has meaning
12 in terms of reasonableness of their actions, et cetera.

13 So we are not asking the Court to command the
14 jury that this is truth. That's a very different thing.
15 But -- and the examples that we can give you and the
16 cases make that very point.

17 THE COURT: It's a subtle distinction.

18 MR. WILSON: Whether the website says it is a
19 risk factor or says it is not a risk factor, the document
20 is still being offered for its truth and it's being
21 offered for showing the absence of the statement.

22 THE COURT: But the problem that Mr. Williams is
23 identifying is this: Plaintiff is asserting a theory
24 that the defendants had an obligation to warn, that there
25 was sufficient information in the community that they
26 should warn. The fact that a government agency thinks
27 there is not sufficient evidence goes properly to their
28 state of mind.

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1 MR. WILSON: Your Honor, we have heard no
2 evidence for -- any Johnson & Johnson witness saying that
3 the reason why we didn't provide a warning is because the
4 NCI said that talc was not a risk factor.

5 I think to -- and as Mr. Smith notes, for the
6 vast majority of the time, up until just about a month
7 before trial, talc was listed as a risk factor.

8 THE COURT: There's an argument to the jury
9 about that.

10 MR. WILSON: I think the Court's original
11 analogy pointing to this type of evidence as being like a
12 request for judicial notice as to the truth of what is
13 stated in a court record is directly on point.

14 THE COURT: Well, if counsel has cases you want
15 me to look at, I'm happy to look at them. So if you can
16 either file a very, very short brief --

17 MR. WILLIAMS: We will.

18 THE COURT: -- that consists only, perhaps, of
19 the names of cases.

20 MR. WILLIAMS: That's right, your Honor.

21 Finally, on the portions of the transcripts,
22 here is what we are saying there. Prior inconsistent
23 statements come in for the truth of the matter asserted.

24 Our point was to merely keep track of all of the
25 times that there was impeachment read into the record
26 that consisted of prior inconsistent statements under
27 oath. We do not seek to have those portions to go back
28 to the jury.

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1 What we were simply trying to do was to keep
2 track for the Court, counsel, the parties of all of those
3 instances, because if there were to be a request for a
4 readback, they could easily be identified and they could
5 be read back to the jury. That's all that we were doing
6 by putting those -- chronicling those on the exhibit
7 list.

8 So, to be clear, we're not claiming that they
9 should be copied and go back as exhibits.

10 MR. WILSON: If that's what they want to do, I
11 think they can make the point in closing argument and
12 they can point to the portion of the transcript. If the
13 jury thinks it's significant, they can write that down
14 and ask for a readback if they are interested.

15 THE COURT: Right. I just don't think the
16 transcripts themselves go back to the jury.

17 MR. WILSON: Exactly, your Honor.

18 MR. ROBINSON: Your Honor, I have one question
19 about what we just discussed raises. So in final
20 argument, both sides would be able to cite from the
21 transcript.

22 THE COURT: Sure.

23 MR. ROBINSON: That's fine.

24 MR. SMITH: In closing statement we can put
25 trial transcript testimony up?

26 THE COURT: Yeah.

27 MR. SMITH: Okay.

28 THE COURT: Let me ask an unrelated question but

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1 perhaps related. Have counsel talked about what you want
2 to do on the negligence per se instruction? I know when
3 we started there was an agreement not to reference the
4 FDA issue in opening. Has there been further discussion
5 about that? Because that in part bears on this nonsuit
6 motion.

7 MR. ROBINSON: Mr. Wilson has a brief on that,
8 your Honor.

9 MR. WILSON: So, your Honor, we had proposed a
10 CACI 418 instruction modeled after exactly the way the
11 framework of the CACI 418 instruction is set forth in the
12 Judicial Council jury instructions. Based upon 740.1(a),
13 we believe that it would read something to the effect of
14 "Title 21, Section 740.1(a), the Code of Federal
15 Regulations states" -- and then verbatim provide that
16 regulation.

17 And then this is -- and again, we maybe have to
18 modify this based upon the fact we have two defendants,
19 but the second element, we never really talked about this
20 when we previously talked about negligence per se or
21 740.1(a).

22 There was an argument about how this instruction
23 shouldn't be given because it doesn't have a causation
24 component, but it does, and it is that the violation has
25 to be a substantial factor in bringing about the harm
26 suffered by the plaintiff. Then you must find the
27 defendant was negligent unless you find the violation was
28 excused.

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1 It goes on to say that this is -- if you don't
2 find negligence under this theory, you have to still look
3 at the other instructions.

4 THE COURT: Here's the problem with this
5 instruction. Everyone tells me that it's reversible
6 error per se not to follow CACI. Let me remind you that
7 the instructions for CACI say that they should be
8 modified appropriately for a case.

9 The problem with the negligence per se
10 instruction in this context is the substantial factor
11 language because to read the instruction as it is, first
12 of all, the jury might reach the conclusion that there
13 was no warning, Ms. Echeverria used the product, done.
14 There is liability. That's not the law.

15 MR. WILSON: I think, your Honor, the other
16 instructions that we have make it clear that that would
17 not be sufficient for the imposition of liability so that
18 the failure to provide the warning is not enough.

19 THE COURT: Not only is it not enough, but she
20 has to prove that the cancer --

21 MR. WILSON: Correct, your Honor. We have the
22 other instructions --

23 THE COURT: Right. But you didn't --

24 MR. ROBINSON: More probable than not could
25 change the concern about substantial factor.

26 THE COURT: But the problem is that the
27 language -- the violation was a substantial factor is
28 really not sufficient in this context because it's not

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1 simply the violation. There also has to be proof that
2 the cancer is caused by the product.

3 MR. SMITH: Sure.

4 MR. WILSON: But rather than just saying in
5 light of that modification, that is appropriate, let's
6 not give this instruction at all; let's modify it in a
7 way that I think addresses the Court's concern.

8 THE COURT: Well, you can take a stab at that.
9 But that's the big problem here, I think.

10 MR. WILSON: Okay. Fair enough. We agree.

11 MR. WILLIAMS: Your Honor, we have discussed
12 this several times.

13 THE COURT: We have been around about it.

14 MR. WILLIAMS: And I just wanted to remind the
15 Court where we were. And so I thought that this might
16 come up, and so I have a transcript from that which I
17 think crystalizes the issue. If I may.

18 First of all -- and this is -- for the record,
19 this is the transcript from July 26, 2017. And this is
20 the comment of the Court.

21 "The law is clear, but there is a
22 question of how it's going to be applied
23 here. You can talk to counsel for a
24 second. If he wants to not mention
25 anything about the FDA regulation in his
26 opening statement, and we don't have to
27 think some more about this, that's okay.

28 "But, otherwise, I think the

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1 defense has the better of the argument
2 here, that the -- that, first of all,
3 it's really not dicta in Valentine, in
4 my view, and it's all a part of what the
5 duty to warn is.

6 "So if you would rather not talk
7 about 740.1 in your opening statement, I
8 understand that. You've made your
9 record. I understand the problem. I
10 think on this -- this set of facts, and
11 particularly with giving this 'may' --
12 giving the 'may' language in 740.1, it
13 has to be crystal clear to the jury that
14 'may' doesn't mean 'possibly.'"

15 THE COURT: That's the second problem with the
16 instruction.

17 MR. WILLIAMS: And there was an additional
18 discussion, and the Court made clear -- this at page 617,
19 line 4:

20 "Counsel, you have already said it
21 three times."

22 Addressing plaintiff's counsel.

23 "I appreciate what you say. I
24 understand the problem. But I think if
25 you're going to put 740.1 at issue in
26 this case, the jury has to have it --
27 has to have had it made crystal clear to
28 them that 'may' does not mean

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1 'possibly.' Valentine addresses that
2 directly."

3 And that followed, your Honor, my argument that
4 it wasn't just opening statement; it was putting it at
5 issue in the case.

6 You continued and said, "You have made your
7 record."

8 But then Mr. Cachan sought clarification about
9 whether the issue was coming in.

10 "And just to clarify, your Honor,
11 this is the issue coming out of the
12 case. We're not talking about it. It's
13 not going to be in the opening. And
14 we're going to hear a little bit later
15 about some mysterious federal regulation
16 unstated, or 740.1, because, if that's
17 the issue, it's different."

18 And the Court said:

19 "The time is now. The plaintiff
20 has to elect whether they want to" --

21 Then Mr. Robinson spoke up. He asked for 1222
22 and extra language from Valentine. And then the Court
23 said:

24 "Here is what counsel is asking,
25 and this is my question as well: It's
26 not just a question that it's not going
27 to be in opening statement here; there
28 is not going to be any evidence in this

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1 trial on 740.1. Yes or no?"

2 "Mr. Robinson: We'll do it, your Honor.

3 "We'll do what?

4 "We won't go to 740.1, but no

5 Valentine."

6 So that was the issue. The issue was clear that

7 740.1 --

8 MR. ROBINSON: No.

9 MR. WILLIAMS: May I finish, your Honor?

10 THE COURT: Just a minute. Let counsel finish,
11 and then you can respond.

12 MR. WILLIAMS: That 740.1 wasn't going to come
13 in. And so the Court then asked:

14 "So with that in mind, did counsel
15 want me to preinstruct the jury at all?"

16 Mr. Robinson said:

17 "I don't see any reason."

18 Mr. Cachan said:

19 "We don't either, but with this
20 clarification, your Honor, which is we
21 want to make certain that the fact 740.1
22 is no longer in the case doesn't mean
23 that all of a sudden we're prohibited
24 from bringing up the FDA letter,
25 understanding we're not talking about
26 740.1, but the FDA letter should not be
27 affected."

28 And we asked for clarification. The Court then

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1 said:

2 "Right. That's a whole different
3 issue, but we don't have to give that
4 this morning. So if you want to do
5 that, I think it's okay. That's a fair
6 inference from your -- the letter will
7 come in, but I think counsel is entitled
8 to argue that the fact that the FDA does
9 not require a warning because there
10 wasn't inclusive" -- that may have been
11 "conclusive" -- "proof isn't the
12 standard in the state."

13 So our point is 740.1, the statute, the per se
14 instruction that counsel and Mr. Wilson just put up,
15 should not be used. There was that long argument. And
16 you'll remember Mr. Cachan saying it either is the same
17 standard as California or it isn't. If it's the same
18 standard, then it's confusing, for the reasons the Court
19 has said. If it's a different standard, 740.1 cannot
20 change the law. That was the thing that we talked about
21 again and again.

22 So I'm doing my best to channel Mr. Cachan, but
23 the point is that the instruction that they're requesting
24 should not be given, in our view. They made a choice at
25 the beginning of the case whether it was coming in or
26 not. And they should have to live with that.

27 THE COURT: Mr. Wilson.

28 MR. WILSON: Thank you, your Honor.

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1 Everything that counsel just talked about came
2 up in the context of the preinstructions. We were
3 talking about what we were going to preinstruct the jury
4 about. We wanted 418. We wanted 740.1(a). They wanted
5 Valentine and the modified CACI 1220. They got -- what
6 Mr. Robinson was talking about was a tradeoff. We won't
7 ask for the 740.1 preinstruction if they don't get their
8 modified Valentine 1222. They got their way. What they
9 really want now is to have their cake and eat it too.
10 That's what's going on. We never gave up the right to
11 instruct the jury at a later time on 740.1(a).

12 What the Court, I think -- you know, we were
13 talking about also the Cooper instruction that the Court,
14 I think, was weaving into how to appropriately give
15 740.1(a) in this context, with that Cooper instruction
16 that the Court came up with. That is an appropriate
17 compromise here. But to say that we just forfeited the
18 right to ever have the jury instruction on 740.1(a) or to
19 introduce any evidence, that's not what happened. We
20 were talking about preinstructions. We wanted some; they
21 wanted some. They got their way. They got the ones that
22 they wanted; we got nothing that we wanted.

23 THE COURT: Well, you could have had a
24 preinstruction, but you didn't want the preinstruction
25 that I was going to give.

26 MR. WILSON: So we weren't talking about
27 preinstructions at that time, your Honor.

28 MR. WILLIAMS: Respectfully, your Honor, what I

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1 just showed the Court was the Court saying that the time
2 was now for the plaintiff to make that decision. That's
3 what the Court did. They didn't want to have the
4 preinstruction. When faced with the decision about
5 whether to use 740.1 and get an instruction for the jury
6 or not, they chose not to do that. The Court made
7 crystal clear three other places that, if they were to
8 make that choice at that time, the Court was going to
9 give the extra Valentine language in the instruction.
10 They didn't want that. They made that choice.

11 What they're asking for now is to try to -- I
12 guess, the passage of time and the fading of memory,
13 they're trying to now say that 740.1 is front and center
14 in the case. That's not what happened. The Court told
15 them that they had to make a decision. The decision was
16 made. The question at the end of the discussion was
17 whether or not 740.1 is coming in the case or not, not
18 just opening statement.

19 MR. WILSON: Your Honor, we were talking about
20 preinstructions. They got the preinstruction that they
21 wanted. We didn't -- 740.1 wasn't preinstructed. There
22 was never an agreement that it was never going to be
23 instructed at the conclusion of the case. To call it a
24 centerpiece of the case is not accurate. It is part of
25 the claims. It is part of the instructions. It's part
26 of the evidence in the case. We're going to hear about
27 it shortly from the witness that's on the stand right
28 now.

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1 And, you know, we would just ask that we be
2 allowed to permit what we believe is an appropriate set
3 of final jury instructions, including the very CACI -- or
4 the 740.1 instruction, as well as maybe the Cooper issue,
5 to address how to appropriately put this before the jury.
6 To wipe it out when we were clearly having a discussion
7 where we were proposing a tradeoff, "Look, we won't go to
8 740.1 if you don't do this modified 1222, and we won't
9 talk about it in opening." To say that that's now barred
10 us from including it in the final instructions is not
11 accurate, and it's just not what happened.

12 MR. WILLIAMS: May I?

13 MR. WILSON: Sure.

14 MR. WILLIAMS: One more time, your Honor. It is
15 what happened. The transcript doesn't lie. This is
16 page 620.

17 "The Court: Mr. Robinson, here is
18 what counsel is asking and this is my
19 question as well: It's not just a
20 question that it's not going to be in
21 opening statement here. There is not
22 going to be any evidence in this trial
23 on 740.1. Yes or no?

24 "Okay, your Honor. We'll do it,
25 your Honor.

26 "You'll do what?

27 "We won't go to 740.1, but no
28 Valentine."

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1 The choice was made at that time that 740.1 was
2 in or out of the case. Counsel just mentioned -- this
3 shows exactly what they planned. We're not going to talk
4 about 740.1 with Dr. Andersen. Counsel and Mr. Wilson
5 just mentioned a minute ago that they plan to try to do
6 740.1 with Dr. Andersen.

7 MR. ROBINSON: Your Honor --

8 MR. WILLIAMS: That's not in the case. The
9 choice was made at that time. The Court gave them a
10 choice. It was about whether it's coming into the case.
11 It could not be clearer.

12 MR. ROBINSON: Your Honor, later, the Court --
13 whatever happened here, the Court put the Valentine
14 instruction in. So all bets were off.

15 THE COURT: The Court put the Valentine
16 instruction in because Mr. Smith --

17 MR. ROBINSON: Yes, that was the condition.

18 THE COURT: That was different. Mr. Smith made
19 reference in the opening statement, if I recall
20 correctly, to separate -- that causation need not be
21 shown here. That is why they were preinstructed with the
22 Valentine instruction.

23 MR. ROBINSON: Your Honor --

24 THE COURT: That's different.

25 MR. ROBINSON: But, your Honor, what I'm saying
26 is, that's why I -- whatever the reason was, Valentine
27 was put in. So I'm just saying that that was the only
28 reason I was saying in my opening statement I wasn't

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1 going to mention 740.1. The bottom line is 740.1 is the
2 law -- federal law on this case, your Honor. And,
3 basically, Valentine was read in. So I think 740.1 is
4 what should be given to the jury.

5 THE COURT: All right. So my recollection has
6 been refreshed about this point. Thank you.

7 MR. WILSON: Your Honor -- I'm sorry. This was
8 a discussion about a tradeoff.

9 THE COURT: Okay. Excuse me, Counsel.

10 MR. WILSON: I'm sorry.

11 THE COURT: At the very beginning of this, there
12 was a discussion about whether 740.1 was going to be in
13 the case or not in the case. And if it was -- if it was,
14 what instruction we were going to give the jury at the
15 beginning so that they would understand the context of
16 740.1 and not be under the misimpression that the word
17 "may," as used in this statute, was mandatory or wiped
18 out any "likely/more probably than not" requirement and
19 causation still had to be proven.

20 Plaintiff elected not to go with 740.1. I read
21 the Valentine instruction later as a curative instruction
22 because of the statements that were made in opening
23 statement.

24 Defense counsel is correct. I'm not going to
25 instruct on 740.1. You elected out of it.

26 MR. WILLIAMS: For clarity, your Honor, it would
27 not be appropriate for Mr. Smith on cross-examination to
28 put 740.1 in front of Dr. Andersen when I'm not going

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1 there at all, not raising that at all. It would be
2 inappropriate. 740.1 should be out of the case, and the
3 jury should not be confused on the issue.

4 MR. SMITH: Your Honor, it's in his report. He
5 relies on it in the four corners of his report. It's not
6 like Dr. Plunkett. I understand why the judge said --
7 Dr. Plunkett didn't work at the FDA, didn't have specific
8 knowledge. He says he knew everything and worked in
9 every department of the FDA. He has 740.1(a) quoted in
10 his report, and the basis of his opinions through his
11 deposition are in the four corners of his report. That
12 is a different story.

13 They elected to bring this witness. They didn't
14 have to bring him. But if we're talking about the
15 opinions -- if I've been stuck to the four corners of my
16 experts' reports, what's good for me ought to be good for
17 them. And they elected to bring this witness, and he
18 relies on it and quotes it in his report.

19 MR. WILLIAMS: Your Honor, he is giving no
20 opinions regarding 740.1. We have been -- he's not
21 giving any opinions regarding FDA. We established that
22 he worked at the FDA. The opinions that he is giving
23 relate to the CIR and they relate to the safety of talc.
24 We are not giving that opinion.

25 The reason that it was in his report is that we
26 knew that they -- specifically, Dr. Plunkett -- had
27 intended to give all kinds of opinions concerning 740.1.
28 In his report, Dr. Andersen says that he's giving

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1 responsive opinions.

2 THE COURT: May I see the report?

3 MR. WILLIAMS: Sure.

4 MR. SMITH: Here you go, your Honor. May I
5 approach?

6 THE COURT: I don't have a notebook -- let me
7 just -- do you have a complete notebook for Dr. Andersen
8 that the Court can have? If it's in the notebook, I'll
9 just get it. Is the report in there?

10 MR. WILLIAMS: It is.

11 THE COURT: Okay.

12 MR. WILLIAMS: Or I believe it is.

13 MR. SMITH: Further, your Honor, I just want to
14 make another point on this while you're reading to give
15 some context. He says that all his reliance materials
16 for the basis of his opinion are in his report. He went
17 and read Mr. Steinberg and Dr. Plunkett's prior
18 deposition testimony and report where it lays out
19 740.1(a), and then he cites it in his report and
20 interprets 740.1(a).

21 I'm not going to ask him to interpret a statute.
22 You said that invades the province of the jury. But to
23 say somehow that 740.1(a) isn't in here when it's both in
24 Mr. Steinberg's deposition and report, Dr. Plunkett's
25 deposition report -- which he says he relies on -- and
26 then cited and quoted in the four corners of his report,
27 is ridiculous.

28 And, you know, again -- I will say again, your

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1 Honor, they did not have to call this witness and put
2 this at issue. Just because they didn't bring it up on
3 cross doesn't erase it that he's relied on it in his
4 reference materials and it's cited in his report.

5 MR. WILLIAMS: Your Honor, may I walk you
6 through this?

7 THE COURT: Sure.

8 MR. WILLIAMS: First of all, at the bottom of
9 page 3, if you have D25 in front of you, your Honor.

10 THE COURT: I do.

11 MR. WILLIAMS: At the bottom of page 3, it says:

12 "I anticipate testifying at trial
13 regarding the assessment of the safety
14 of talc as used in cosmetics, the issue
15 of the use of scientific data in making
16 safety assessments in general and the
17 procedures used by the CIR in
18 particular, and the role of
19 manufacturers in such safety
20 assessments. I also anticipate
21 responding to the opinions and testimony
22 offered by the plaintiff's experts in
23 this case."

24 If you then turn back to the later portion where
25 it references Dr. Plunkett and Mr. Steinberg, and that's
26 on page --

27 THE COURT: Can you tell me where that is,
28 please?

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1 MR. WILLIAMS: If you'll bear with me.
2 Dr. Plunkett is on page 16 of D25, paragraph 10. What
3 the doctor did, Dr. Andersen, was he went through the CIR
4 report. He then says that he is going to be responsive
5 to Steinberg and Plunkett. On paragraph 10 he cites the
6 October 5, 2006, expert report of Dr. Plunkett and all of
7 her statements about 740.1, which you will see on page 17
8 at the top. You'll see it says up there at the top:

9 "It is informative, therefore, that
10 FDA has denied two petitions," et
11 cetera.

12 So, your Honor, this portion was responsive. Of
13 course, Dr. Plunkett, the Court kept that out. So there
14 has been no opinion given by Dr. Plunkett on 740.1.
15 Dr. Andersen was going to respond to those opinions, as
16 we had to have him do, because, in other cases, 740.1 was
17 front and center in the plaintiff's theory. They tried
18 to make it front and center here. The Court disagreed
19 and disallowed Dr. Plunkett's testimony in that regard.

20 After that, we had the colloquy that's up on the
21 board right now, where the Court said, "You have to
22 decide" -- plaintiff's counsel -- "whether this is coming
23 in or it is not." So to simply say that it's in
24 Dr. Andersen's report when it's in his report as a
25 response to potential testimony of the expert on the
26 other side, what were we to do? The plaintiffs intended
27 to make that argument. We had to be in a position to
28 respond.

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1 But that is not the opinions that he has given
2 in this case. We do not intend to elicit it from him.
3 It would turn the rule on its head to simply say that the
4 fact that we put it in our report responding to what
5 their expert planned to do means that it automatically
6 becomes an issue in the case. That is what makes no
7 sense, with all due respect to plaintiff's counsel. It
8 is not simply that the word is in the report. It was
9 there for a reason. It was there to respond to
10 Dr. Plunkett. Dr. Plunkett has not been permitted to
11 make that testimony.

12 THE COURT: Do you want to make your argument
13 about Mr. Steinberg? It's the same, I assume.

14 MR. WILLIAMS: Well, it was the same with
15 Steinberg. They chose not to call him in the case.

16 So either way you look at it, the fact that this
17 is in the report should not obviate everything that we
18 went through, the weeks of argument on 740.1, where the
19 Court made them make a decision.

20 The sequence was, after the Court made them make
21 a decision, they said no, as you can see up on the board,
22 on line 12, on page 620 of the transcript. Mr. Smith
23 then injected it again into opening statement,
24 distinguishing "may" language from causation. The Court,
25 in reaction to that, after having agreed not to give the
26 Valentine instruction, gave the Valentine instruction.

27 So this is of their making; it's not of our
28 making. Now they're trying to inject it in through this

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1 witness again when their expert was prevented from doing
2 it. Ours was simply to be responsive.

3 MR. SMITH: Your Honor, what's good for the
4 goose is good for the gander. I mean, I've had to stay
5 within the four corners of my report. It is cited. It
6 doesn't matter -- he gives an opinion on it.

7 But beyond even that, he said he relies on, for
8 the basis of his opinions, the report of Mr. Steinberg,
9 the deposition of Mr. Steinberg was exclusively
10 mentioned, and Dr. Plunkett's deposition and her report,
11 which continually talked about it. It --

12 THE COURT: Excuse me.

13 MR. SMITH: I'm sorry.

14 THE COURT: Can you tell me where in
15 Dr. Andersen's report he relies on Dr. Steinberg or
16 Dr. Plunkett with respect to his opinions regarding the
17 CIR safety assessment? That's the first part of the
18 report. And if he tells us what his point of view is
19 about that.

20 MR. SMITH: I don't think the CIR report is at
21 issue, your Honor, that we are talking about. I think
22 it's more on page 16 and 17 of his report.

23 THE COURT: Right. But that is, as he makes
24 clear on page 3, rebuttal to the opinions and testimony
25 offered by plaintiff's experts in this case. That's what
26 it says. That's what the report says.

27 So if your -- since Dr. Plunkett didn't talk
28 about the FDA and Dr. Steinberg -- is it Dr. Steinberg?

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1 MR. SMITH: Mr. Steinberg.

2 THE COURT: Mr. Steinberg wasn't called as a
3 witness. There's nothing to rebut. No part of the
4 report really needs to deal with that.

5 MR. SMITH: Okay. Give the defense that.
6 That's fine. But look at Number 2 under page 3, "Other
7 Materials." He went not just as rebuttal to -- he went
8 and said:

9 "Other materials that he's relied
10 on: expert report and deposition of
11 David Steinberg; expert report and
12 deposition of Laura Plunkett; the Hill
13 criteria; the FDA website, which has
14 this on it; consent judgment."

15 He went to the FDA website. It has this 740.1
16 language on it. "Consent judgment involving the people's
17 claim against defendant Glive [phonetic]. Description of
18 clinical trials." So it's on the website he also said he
19 went to besides just rebuttal testimony of Steinberg and
20 Dr. Plunkett.

21 THE COURT: But the information he deals with,
22 the testimony that was anticipated to be given by
23 Dr. Plunkett and Mr. Steinberg, if counsel doesn't bring
24 that out, I don't think it's proper given the scope of
25 plaintiffs.

26 MR. SMITH: Even though he was at the FDA, he's
27 aware of warnings, he said went to the FDA website, he
28 has reliance materials on his report outside

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1 Mr. Steinberg or Dr. Plunkett.

2 THE COURT: The problem, Counsel, is that if he
3 doesn't give an opinion on that issue, there's no -- it's
4 outside the scope of his opinion.

5 MR. SMITH: Well, the defense counsel just filed
6 a pleading to take judicial notice of the 2014 citizen's
7 petition that has it in it.

8 MR. WILLIAMS: Your Honor, these are two totally
9 separate issues. I'm not going to talk about the 2014
10 issue that we just filed the judicial notice on at all
11 with Dr. Andersen.

12 As the Court indicated, and I showed just a few
13 minutes ago, we specifically raised the issue of whether
14 or not 740.1, the fact that that is not coming into the
15 case, would prevent us from putting in the FDA letter.
16 That was this portion of the transcript at page 627 of
17 the transcript on July 26 where Mr. Cachan raised the
18 issue. And the Court said:

19 "That's a whole different issue,
20 but we don't have to go into that this
21 morning. If you want to do that, I
22 think it's okay. That's a fair
23 inference from your -- the letter will
24 come in. But I think counsel is
25 entitled to argue that the fact that the
26 FDA does not require a warning, because
27 there wasn't inclusive proof" -- that
28 might have been "conclusive" -- isn't

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1 the standard in the state."

2 So the point is that the issue of whether or not
3 we separately can put in and have the Court take judicial
4 notice of the fact that the FDA denied a citizen's
5 petition relating to talc, which is a key issue as to our
6 state of mind, as to the state of play we are in talc,
7 that's a different thing from whether or not counsel gets
8 to put 740.1 into the case through a witness where the
9 witness is not giving that testimony.

10 So to respond directly to what counsel said
11 about listing the references, of course the witness has
12 to list all of the references. But the references he was
13 pointing to were references in response to Dr. Plunkett
14 and Mr. Steinberg.

15 MR. SMITH: The reason we didn't go to 740.1(a)
16 with Dr. Plunkett is because we were under the impression
17 the Court was going to read the statute to the jury, and
18 there was no email interpretation, number one.

19 Number two, they want to take judicial notice of
20 an FDA letter that spells out 740.1(a) and (b), but then
21 I'm not able to use it. It makes no sense.

22 THE COURT: If you're going to -- well, I'm
23 going to have to take a look at the letter again. Where
24 is it?

25 MR. WILLIAMS: I don't have a copy on me.

26 MR. SMITH: I've got a copy.

27 MR. WILLIAMS: The letter does not cite 740.1.
28 It uses the language of 740.1, and the writer from the

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1 FDA says that:

2 "Based on the totality of the
3 evidence that's in front of the FDA, we
4 do not believe that a warning is
5 required on this state of evidence with
6 respect to talc."

7 It does not cite -- and I think it's very
8 intentional that they do not cite the regulation. They
9 simply use the language -- borrow the language from the
10 regulation in saying what they are finding.

11 So the Court separated the two issues when we
12 discussed this very same thing, said that the letter does
13 come in -- the letter comes in, but this opinion they're
14 trying to elicit through this witness should not.

15 MR. SMITH: Okay. Maybe I won't say 740.1(a).
16 But if you'll read the second paragraph, they want to
17 take judicial notice of -- read the second full
18 paragraph, your Honor, please.

19 Can't state it any clearer.

20 THE COURT: No, you can't.

21 So here's the problem: The letter that you want
22 the Court to take judicial notice of says the following:

23 "We have carefully considered both
24 of your petitions. We are committed to
25 the protection of the public health and
26 share your interest in reducing the risk
27 of ovarian cancer. Current regulations
28 state that cosmetic products shall bear

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1 a warning statement whenever necessary
2 or appropriate to prevent a health
3 hazard that may be associated with a
4 product. FDA may publish a proposal to
5 establish a regulation prescribing a
6 warning statement on behalf of a
7 petitioner if the petition is supported
8 by adequate scientific basis on
9 reasonable grounds."

10 MR. SMITH: That's 740.1(a) and (b).

11 THE COURT: Okay.

12 "After careful review and
13 consideration of the information stated
14 in your petitions," et cetera --

15 I'm going to skip some of this.

16 -- "FDA did not find that the data
17 submitted presented conclusive evidence
18 of a causal association between the talc
19 use in the perineal area and ovarian
20 cancer. For this reason and additional
21 reasons described below, FDA is denying
22 your petitions."

23 It goes on.

24 If you're going to put the FDA language before
25 the witness -- well, if you're going to ask the Court to
26 take judicial notice of the fact of the letter, that
27 would be one thing; namely, that there is such a letter.
28 The -- but the letter does state what the position of the

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1 FDA is about what the regulations state. So it's
2 conceivable to me, depending on what Dr. Andersen says in
3 his direct, that there will be room to cross him on this.
4 I don't know what he's going to say, but --

5 MR. WILLIAMS: Dr. Andersen is not giving any
6 opinions regarding warnings. He is not giving any
7 opinions regarding regulation. He is not doing any of
8 that. That was going to be responsive to a possible
9 opinion of Dr. Plunkett.

10 As you know, your Honor -- I'm almost done with
11 him. And he has talked about the CIR and only about the
12 CIR. So we're not going to put it in front of him. To
13 permit them to cross-examine him on it would be
14 inappropriate.

15 The only reason for doing it would be to blur
16 the lines between the language, which you will see there
17 is interpreted as causal, and the "may" language from
18 740.1. It's exactly the same thing that plaintiff's
19 counsel has done repeatedly, which is why the Court gave
20 the instruction it did at the beginning.

21 The reason why we're here is because -- and the
22 reason Valentine was given was because plaintiff tried to
23 do precisely that by blurring it. The only reason that
24 counsel would want to put that in front of Dr. Andersen
25 would be to try to blur the line again and to emphasize
26 the "may" language and to try to suggest to the jury that
27 there was some duty to warn because the regulation uses
28 the word "may," which is exactly the vice that the Court

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1 said should not happen because that's not the law that
2 the jury is supposed to be deciding in this case.

3 So, again, they shouldn't be permitted to inject
4 this into the case. That is a different question from
5 taking judicial notice of the denial of the citizen's
6 petition.

7 MR. SMITH: He wants judicial notice of the
8 denial but not what the rest of the language is. This
9 witness has got up and said "I work at the FDA. I was in
10 every department. I'm a labeling expert." He said
11 "labeling expert." And for me to be hamstrung now
12 because he has talked about all his experience -- this is
13 not Dr. Plunkett that didn't work at the FDA, didn't say
14 "I worked in every department, that I worked on labeling,
15 and I'm a labeling expert and know all this information."
16 For me not to say "you don't know the information" or
17 "you don't know about the citizen's petition" or what
18 that language says that they want to take judicial notice
19 of, it defies legal logic.

20 THE COURT: I'm not exactly clear, Mr. Smith, on
21 how you intend to -- what you intend to do here.

22 MR. SMITH: Can we just take it as it goes and
23 see how it goes? I mean --

24 THE COURT: Well, I think we may have to do
25 that. But the problem I see is two-fold. If the witness
26 doesn't testify to any FDA warning anything, all he said
27 is "I used to work for the FDA and worked my way up the
28 ladder in these various positions, including the

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1 labeling," that if you are going to try to cross-examine
2 him on his expertise because he doesn't know about this
3 letter or something, that might be one thing, but --
4 although I have to say I think it's written after he left
5 the FDA --

6 MR. WILLIAMS: True.

7 THE COURT: -- so how he would know about it
8 is --

9 MR. SMITH: Well, he says he stays up with the
10 FDA and talks to his people back all the time.

11 I mean, look, we can take it up as it goes. If
12 I can't lay the foundation to do it, well, then I'm sure
13 there will be an objection and I can't do it.

14 MR. WILLIAMS: Well, now, here's the thing, your
15 Honor, that's not fair, because he's duty-bound to give
16 honest answers.

17 If Mr. Smith is permitted to go down this path
18 and to ask him questions about labeling, his experience
19 with labeling, of course he's going to say that he has
20 experience with labeling. And then Mr. Smith is going to
21 argue that the door has been opened and that he has laid
22 a foundation and go plunging into 740.1. That's not
23 appropriate.

24 THE COURT: Let's see where we go here. But
25 remind the plaintiff's counsel that from what's in the
26 record, you've made this issue on 740.1, you've made your
27 choice. The Court, I think, has been very, very clear
28 that it is not to be suggested in any way to the jury

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1 that this FDA regulation or its use of the word "may" is
2 to be interpreted in a way that precludes causation.

3 MR. SMITH: I agree. I totally agree.

4 MR. WILLIAMS: He agrees each time, your Honor,
5 and then he does exactly the opposite.

6 THE COURT: Mr. Smith, all I can say is that
7 you've heard what I have to say.

8 MR. SMITH: Yes, your Honor. Thank you.

9 MR. ROBINSON: Your Honor, another matter, I
10 think -- in fairness, I think I should be able to make --
11 to clear something up on the record.

12 Originally when we offered Dr. Plunkett to
13 testify regarding 740.1(a), the Court said, "No. I will
14 read 740.1(a) into the record."

15 Now, the defense then wanted Valentine. And so
16 in exchange for no Valentine, I said -- we were talking
17 about opening statement, but I said, no, no 740.1(a).

18 And then -- but what happened is the Court then
19 read Valentine. So now the, you know, the concession
20 that I wanted, no Valentine, was taken away. I think
21 that automatically puts back 740.1(a) into the case.

22 THE COURT: Counsel --

23 MR. ROBINSON: That's why I think it should be a
24 negligence per se issue, your Honor.

25 THE COURT: I disagree with you. The reason the
26 Court read Valentine was because in the opening statement
27 plaintiff's counsel suggested to the jury it would not
28 have to make a causation finding.

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1 Is the jury ready?

2 COURT ASSISTANT: Yes.

3 (The following proceedings were
4 held in open court in the presence of
5 the jury:)

6 THE COURT: Good morning everyone.

7 ALL: Good morning.

8 THE COURT: Everybody doing okay?

9 ALL: Yes.

10 THE COURT: All right. Good morning. Let's
11 have a seat. We have all the jurors here, two
12 alternates, all trial counsel, Dr. Andersen on the stand.

13 Mr. Williams.

14 MR. WILLIAMS: Thank you, your Honor.

15 DR. ALAN ANDERSEN,
16 having been previously sworn, resumed the stand and
17 testified further as follows:

18 DIRECT EXAMINATION (Resumed) (9:47 A.M.)

19 BY MR. WILLIAMS:

20 Q Good morning, Dr. Andersen.

21 A Good morning.

22 MR. WILLIAMS: Good morning, everybody.

23 ALL: Good morning.

24 BY MR. WILLIAMS:

25 Q Dr. Andersen, at the end of the day -- is the
26 mic working?

27 THE COURT: I don't think so.

28 MR. WILLIAMS: I think it is.

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1 BY MR. WILLIAMS:

2 Q Dr. Andersen, at the end of the day yesterday,
3 we ended by discussing one of the studies focusing in on
4 the Hamilton study, which was one of the studies cited by
5 the Cosmetic Ingredient Review.

6 Do you remember that?

7 A Yes.

8 Q I don't want to take the time to go into the
9 specifics of the following studies, but I do want to just
10 mention them and ask you this question: Did the Cosmetic
11 Ingredient Review have available to it and review the
12 scientific study known as Buz'Zard, which is
13 Exhibit L131, when it reached its conclusions as set
14 forth in the CIR report?

15 A Yes, it did.

16 Q It did?

17 COURT ASSISTANT: Excuse me, Counsel. The jury
18 can't hear you.

19 THE COURT: Thank you.

20 MR. WILLIAMS: I thought it was working. Hello.

21 THE COURT: There you go. Now it's working.

22 MR. WILLIAMS: Is that better? I'll try here,
23 but when I put it on my tie, it rustles a lot.

24 Is this better?

25 THE COURT: It was there for a second and then
26 it went out again.

27 MR. WILLIAMS: Hello.

28 THE COURT: There you go.

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1 UNKNOWN JUROR: We hear you.

2 MR. ROBINSON: Loud and clear.

3 BY MR. WILLIAMS:

4 Q Okay. Let me ask that again. Was the
5 scientific study known as Buz'Zard, which is Exhibit
6 L131, available to and reviewed by the CIR expert review
7 panel at the time they reached their conclusions
8 regarding talc?

9 A Yes, it was.

10 Q Was the scientific study known as the Shukla
11 study, L1138 in this case, from 2009, was that scientific
12 study available to and reviewed by the Cosmetic
13 Ingredient Review?

14 A Yes. That was part of what we looked at.

15 Q Let me turn to another couple of studies.

16 Did the CIR consider studies looking at whether
17 talc causes what's known as adverse cellular effects in
18 human cells?

19 A Yes. There were several studies that looked at
20 human cells in laboratory culture and looked at the
21 effects.

22 Q Was one of those studies a study called Nasreen?

23 A Yes, it was.

24 MR. WILLIAMS: For the record, your Honor,
25 that's Exhibit L887.

26 BY MR. WILLIAMS:

27 Q Dr. Andersen, was one of the scientific studies
28 reviewed by the CIR the study called Lee?

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1 A Yes.

2 Q That's Exhibit L741.

3 Did the CIR find that there were any adverse
4 cellular effects relating to talc?

5 A Not in the cellular studies that were reported.

6 Q Please go ahead.

7 A I think the phrase that the panel adopted was
8 the cellular studies were unremarkable.

9 Q If you could look in your book, the first book,
10 at Exhibit D25.

11 A I'm sorry, E?

12 THE COURT: E or D?

13 MR. WILLIAMS: D as in dog. D25.

14 BY MR. WILLIAMS:

15 Q Which is your report, which attaches the --
16 which attaches the study.

17 Do you have that in front of you?

18 A None of these have a D.

19 Q I know what it will have. Why don't you take a
20 look at Exhibit L384, which is the published version of
21 the study.

22 A Yes.

23 Q We can use that.

24 Let me direct your attention to page 11 of
25 Exhibit L384.

26 A Yes.

27 Q And for the record, we are referring to the
28 final final report of CIR.

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1 Do you see the heading there on page 11,
2 "Cellular Effects"?

3 A Yes, I do.

4 Q And a few moments ago, without the report in
5 front of you, I believe that you used the phrase "No, not
6 remarkable"?

7 A That's correct.

8 Q Was this the portion of the report that you were
9 referring to?

10 A Yes, it was.

11 Q Can you describe for the members of the jury
12 what the CIR concluded with reference to cellular
13 effects?

14 A They didn't really inform the discussion about
15 the safety of talc as used in cosmetics.

16 Q In the report that's in front of you, you see
17 that there are some citations? There's a reference
18 number at the end of the paragraph on cellular effects?

19 A Yes.

20 Q Do you see that it refers to 69 and then 71
21 through 78?

22 A That's correct.

23 Q Could you just flip to the back to the
24 references of the studies that were referenced and verify
25 that the Lee and Nasreen studies were among that range of
26 references?

27 A Yes, they are.

28 Q Did you prepare a slide that summarized the

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1 findings of the Nasreen and Lee studies?

2 A Well, presented a picture of what the results
3 look like, yes.

4 Q Like this? Did you do your slide deck?

5 A Yes.

6 Q Do you have that in front of you?

7 MR. WILLIAMS: All right. Your Honor,
8 permission to publish Slide 9 with the Nasreen and Lee.

9 MR. SMITH: Again, it's not in the four corners
10 of his report. Objection.

11 THE COURT: Overruled.

12 BY MR. WILLIAMS:

13 Q Now, with respect to the Nasreen study, can you
14 describe what -- there's been some testimony earlier,
15 Doctor, regarding what we've been calling apoptosis, but
16 can you describe what apoptosis is.

17 A Well, apoptosis is programmed cell death. For
18 whatever reason, a cell has accumulated some level of
19 insult and, as a result, it dies.

20 Q With respect to the Nasreen study, what was the
21 conclusion of that study with regard to the impact of
22 talc on human cells?

23 A Well, the authors were studying in particular
24 the practical aspects of the medical procedure called
25 "pleurodesis" in which talc is actually injected into the
26 area around the lung for a clinical benefit.

27 And in doing the study, they didn't look at
28 people. They took lung cancer cells in a laboratory in a

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1 culture dish, and they took normal lung cells in culture
2 in a petri dish in a laboratory, and they exposed them to
3 talc. And this captures the exposure to talc resulted in
4 an increase in apoptosis in the cancer cells, but it
5 didn't affect the normal cells.

6 Q With respect to the Lee study, was that a
7 similar type of analysis?

8 A As I read it, the Lee study was actually a
9 letter to the editor, not a full published -- it was
10 published, but it was just a letter to the editor
11 repeating virtually the same finding, that talc affected
12 the lung cancer cells but didn't affect normal cells.

13 Q So the effect that the -- did the exposure of
14 talc to human cancerous lung cells result in programmed
15 cell death for the cancerous cells?

16 A That's what the studies appeared to say, yes.

17 Q Did the exposure of talc to healthy human cells
18 result in cell death for the healthy cells?

19 A No, it didn't.

20 Q The CIR report was finalized in 2013, was it?

21 A That's correct.

22 Q And the -- what you called yesterday the final
23 report was put on the website in 2013?

24 A That's correct.

25 Q But the publication of the final -- what you
26 called the final final report didn't happen until two
27 years later; correct?

28 A That's correct.

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1 Q You were retained by Johnson & Johnson when?

2 A Mid 2016.

3 Q Between the time that you left the CIR in 2013
4 and the time that you prepared your report for this
5 litigation, did you review studies of different types
6 that came out after 2013 when the CIR report was
7 prepared?

8 A Yes, I did.

9 Q Could you describe just generally the types of
10 studies you reviewed.

11 A Well, I think for the most part the data that
12 were newly available were epidemiology studies.

13 Q Did you review epidemiological studies of both
14 the cohort or prospective type and the retrospective
15 case-control type?

16 A There were examples of both newly published. So
17 I looked at them all.

18 Q In your view, did the studies that you reviewed
19 change the total scientific landscape that you had last
20 studied back in 2013 at the time the CIR report came out?

21 A It -- no, I don't think they changed my view of
22 what the epidemiology data allows you to conclude. It
23 looked much more of the same.

24 Q Based on your review of literature and the
25 analysis that you did both in 2011 through 2013 when the
26 CIR report was prepared, and more recently after you left
27 the CIR and reviewed the studies that you just referred
28 to, Doctor, do you consider talc to be safe in the

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1 present practices of use and concentration?

2 A Yes.

3 Q Does the present practice and use -- strike
4 that.

5 Does the present practice of use and
6 concentration include the perineal use of talc?

7 A Yes, it does.

8 MR. WILLIAMS: No further questions, your Honor.

9 THE COURT: All right. Thanks.

10 Mr. Smith.

11 MR. SMITH: Yes, your Honor. Can I have just a
12 second?

13 THE COURT: Sure.

14 MR. SMITH: Thanks.

15 Your Honor. I have a notebook. May I approach?

16 THE COURT: Sure. That's for the witness?

17 MR. SMITH: May I approach?

18 THE COURT: Yes.

19 MR. SMITH: Thank you. And I have some for you,
20 your Honor. Stack them up.

21 THE WITNESS: Wow. I assume the bigger one is
22 Volume 1.

23 MR. SMITH: Yes. We might not go through all of
24 it. I just had it here just in case.

25 May I approach, your Honor?

26 THE COURT: Yes.

27 MR. SMITH: Thanks, your Honor.

28 Can I switch out Volume 2 with you, Judge? We

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1 are going to get this right. The smaller one. Thank
2 you.

3 THE COURT: Thank you.

4 MR. SMITH: Okay. Has everybody got a copy?

5 Good morning, all.

6 ALL: Good morning.

7 CROSS-EXAMINATION

8 BY MR. SMITH:

9 Q Hey, Doctor, how are you doing?

10 A Doing well so far.

11 Q My name is Allen Smith and I represent
12 Ms. Echeverria. And we haven't had the pleasure of
13 talking, have we, before?

14 A I'm sorry?

15 Q We haven't had the pleasure of talking before,
16 have we?

17 A No, we haven't.

18 Q Well, nice to see you. I just have a few
19 questions for you this morning. Okay?

20 A That's fine.

21 Q I want to start where you just left off with
22 defense counsel on the Lee and Nasreen study, and you
23 talked about how those studies showed that talc caused
24 cancer cells to die.

25 Do you recall that?

26 A Yes, I do.

27 Q And you're familiar with radiation, are you not?

28 A Yes, I am.

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1 Q You said you are an expert in that and had very
2 good -- or very familiar with that -- I thought you said
3 you had specialized knowledge regarding radiation in
4 direct. Did I misunderstand that?

5 A No, you didn't. I spent 22 years with radiation
6 protection as part of my responsibilities, so yes.

7 Q And radiation exposure to humans over a chronic
8 or a long period of time can lead to cancer, can it not?

9 A It depends.

10 Q Sure. But it can; it's possible. Correct?

11 A Yes, it's possible.

12 Q And radiation is used to give to patients like
13 my client to kill cancer cells after surgery; correct?

14 A Radiation of different types are used as part of
15 cancer therapy, yes.

16 Q So a similar cancer-causing substance or
17 exposure radiation given chronically over a long period
18 of time can lead to cancer. They can also be given an
19 acute blast exposure to kill cancer cells. Is that not
20 true? It's regularly administered for that.

21 A It depends on the kind of radiation that you're
22 talking about, but there is a circumstance in which, in
23 particular, ionizing radiation can, when given at high
24 doses, targeted exposure, can effectively treat a tumor,
25 yes.

26 Q And I've got other examples of that. HRT.
27 Chemotherapy. We could go down. There's a long list of
28 agents that, when given acutely in high doses, can cause

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1 cancer cells to die and, when given chronically, can lead
2 to adverse medical effects such as cancer; is that right,
3 Doctor?

4 A The generalization that an exposure that is
5 effective in treating a tumor automatically at low doses
6 has an adverse effect is not a generalization that I'm
7 comfortable with. Ionizing radiation in particular
8 happens to fit that pattern. Exposures at low levels to
9 ionizing radiation does present an incremental increase
10 in cancer risk. So at least ionizing radiation, I'm
11 comfortable that that generalization is true.

12 Q All right. We will stick with radiation then.
13 You talked about epidemiological studies since
14 the 2013 CIR report. Do you recall that?

15 A Yes.

16 Q Are you an epidemiologist?

17 A No, I'm not.

18 Q Okay. But you just spoke about the
19 epidemiological data since 2013 when the CIR came out;
20 correct?

21 A That's correct.

22 Q Okay. Are all your opinions contained in your
23 report and all the materials you relied on for your
24 opinions in this case cited in your report?

25 A I believe so.

26 Q And earlier with defense counsel, you talked
27 about your time with the FDA. What years were you there
28 again? I forgot.

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1 A 1971 to 1993.

2 Q So a long period of time?

3 A It seemed like it.

4 Q Sure. And during direct you talked about how
5 you went to all different types of departments, including
6 cosmetics, and were familiar generally with the FDA, how
7 it works, and even talked about labeling at the FDA. Do
8 you recall that?

9 A Yes.

10 Q And so you have -- or you can speak to matters
11 regarding the FDA and its control or lack of control over
12 cosmetics. You have some familiarity with that, do you
13 not?

14 MR. WILLIAMS: Beyond -- excuse me, your Honor.
15 Objection. Beyond the scope.

16 THE COURT: Overruled.

17 BY MR. SMITH:

18 Q You have some familiarity with that, do you not?

19 A I have a familiarity with FDA's regulatory
20 program for cosmetics.

21 Q Okay. And that includes warning language that
22 goes on cosmetics; correct?

23 A Yes, it does.

24 Q Okay. What is the warning language or warning
25 regulation of the FDA regarding cosmetics?

26 MR. WILLIAMS: Your Honor, objection. Beyond
27 the scope.

28 THE COURT: Sustained.

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1 BY MR. SMITH:

2 Q Did you read -- are you familiar with, since you
3 have issued a report and you said all your materials that
4 you relied on in your report, the 1990 -- 2014 FDA
5 response to the citizen's petition on talc?

6 MR. WILLIAMS: Same objection, your Honor.

7 THE COURT: Sustained.

8 BY MR. SMITH:

9 Q At the FDA, in your tenure there, were you
10 familiar with the language that is included in the
11 regulation regarding cosmetics that you spoke about in
12 your deposition and in your report?

13 MR. WILLIAMS: Same objection, your Honor.

14 THE COURT: Sustained.

15 BY MR. SMITH:

16 Q Are you familiar with the FDA regulations
17 regarding warnings, based on your tenure, your knowledge,
18 and experience at the FDA?

19 A In a broad sense, yes, I'm familiar with the FDA
20 concept of labeling in general.

21 Q Could you tell the jury what a voluntary
22 warning -- or paraphrase voluntary warning language
23 regarding the FDA over cosmetics?

24 MR. WILLIAMS: Objection, your Honor. Beyond
25 the scope.

26 THE COURT: Sustained.

27 BY MR. SMITH:

28 Q Are you familiar with the FDA warning language

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1 regarding voluntary warnings on cosmetics?

2 MR. WILLIAMS: Objection. Asked and answered.

3 THE COURT: Sustained.

4 BY MR. SMITH:

5 Q Based on your general knowledge and experience
6 at the FDA, would you agree with me that it is ultimately
7 the companies and manufacturers that are responsible for
8 the safety and labeling of their products?

9 MR. WILLIAMS: Same objection, your Honor.
10 Beyond the scope.

11 MR. SMITH: Goes to his knowledge, general
12 knowledge.

13 THE COURT: No. Overruled given the testimony
14 that he gave about the formation of the CIR and so on.

15 BY MR. SMITH:

16 Q Would you agree with me that it is the
17 ultimate -- it's ultimately the companies and
18 manufacturers that are responsible for the safety and
19 labeling of their products, cosmetic products?

20 A If we could parse that out into the two pieces
21 of your question. The way Congress set up the Food,
22 Drug, and Cosmetic Act, manufacturers are responsible for
23 ensuring the safety of ingredients used in their
24 products. That's where the responsibility is assigned.

25 The labeling is also the responsibility of the
26 manufacturer, but those are implemented via regulations
27 as opposed to Congress having opined.

28 Q And you are familiar with those regulations, as

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1 you stated before; correct?

2 MR. WILLIAMS: Asked and answered, your Honor.

3 THE COURT: Sustained.

4 BY MR. SMITH:

5 Q So, Doctor, based on your knowledge and general
6 experience at the FDA, a manufacturer of a cosmetic
7 cannot say just because the FDA is not mandating a
8 warning, the company is relieved from placing warnings on
9 its cosmetics products; correct?

10 MR. WILLIAMS: It's beyond the scope, your
11 Honor.

12 MR. SMITH: It's based on his general knowledge
13 at the FDA, your Honor.

14 THE COURT: It is beyond the scope. Sustained.
15 BY MR. SMITH:

16 Q Based on your general knowledge at the FDA, are
17 you familiar with adverse incident reports and the like?

18 MR. WILLIAMS: Same objection, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Are you familiar with any voluntary reporting
22 that has to be done by cosmetic companies regarding their
23 products?

24 MR. WILLIAMS: Same objection, your Honor.

25 THE COURT: Scope. Sustained.

26 BY MR. SMITH:

27 Q While at the FDA, since you said that you dealt
28 in different areas including cosmetics, would you also --

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1 would the FDA also look to what others in the industry
2 were doing regarding labeling of their cosmetics?

3 MR. WILLIAMS: Same objection, your Honor.

4 THE COURT: Sustained.

5 MR. WILLIAMS: Not been any evidence given.

6 BY MR. SMITH:

7 Q You said that you were a labeling expert and you
8 had expertise at this at the FDA; correct?

9 MR. WILLIAMS: Your Honor, may we be heard?

10 THE COURT: Sustained. We don't need to be
11 heard further on this.

12 MR. WILLIAMS: Thank you, your Honor.

13 THE COURT: Mr. Smith.

14 BY MR. SMITH:

15 Q Are cosmetics preapproved by the FDA before they
16 go on the market like drugs?

17 MR. WILLIAMS: Same objection.

18 THE COURT: Overruled.

19 THE WITNESS: As you phrased the question, the
20 answer is it depends.

21 BY MR. SMITH:

22 Q So baby powder has to be preapproved before it
23 goes on the market by the FDA?

24 A No.

25 MR. WILLIAMS: That's argumentative, your Honor.
26 Misstates the question.

27 THE COURT: Sustained.

28 ///

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1 BY MR. SMITH:

2 Q Does baby powder have to be preapproved by the
3 FDA before it went on the market?

4 A No, it does not, unless it contains a color
5 additive. FDA must approve color additives before they
6 go on the market.

7 Q Are you aware if Johnson's baby powder contains
8 a color additive?

9 A I don't know. I just was telling you what the
10 rules are.

11 Q If baby powder, I'll represent to you, is
12 99 percent talc and 1 percent fragrance, would that
13 contain a color additive?

14 A No.

15 Q Would you agree that the cosmetic industry for
16 the most part is self-regulatory?

17 MR. WILLIAMS: Same objection, your Honor.
18 Beyond the scope.

19 THE COURT: Overruled.

20 THE WITNESS: Not in any regard.

21 BY MR. SMITH:

22 Q You don't agree with that statement?

23 A No, I don't.

24 MR. SMITH: Do you have his deposition?

25 BY MR. SMITH:

26 Q Give me just a minute, Doctor. I'm going to
27 pull out my red notebooks.

28 MR. SMITH: May I approach -- I'll give the

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1 defendants --

2 MR. WILLIAMS: Thank you.

3 MR. SMITH: Oh, you need a copy.

4 THE COURT: That's okay.

5 MR. SMITH: Permission to read page -- let me
6 get to it, your Honor. Permission to read line 11
7 through 19.

8 THE COURT: Of what page?

9 MR. SMITH: Oh, I'm sorry. 152.

10 THE COURT: Thank you.

11 MR. SMITH: May I proceed?

12 MR. WILLIAMS: May I have a moment?

13 I'm sorry. What were the line numbers, your
14 Honor?

15 THE COURT: 152, 11 through 19.

16 MR. WILLIAMS: No objection.

17 BY MR. SMITH:

18 Q Question to you -- do you remember being deposed
19 under oath?

20 A Yes.

21 Q A question was asked to you:

22 "Is the cosmetic industry
23 self-regulated?"

24 Your answer was:

25 "That is their intent. It is
26 my" --

27 MR. WILLIAMS: Sorry. I thought that was a
28 stop. I apologize, your Honor. I thought counsel had

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1 stopped.

2 MR. SMITH: May I continue?

3 THE COURT: Yes.

4 BY MR. SMITH:

5 Q Okay.

6 "It is in my own global view as a
7 regulatory scientist with 40 years'
8 experience, it's not entirely true. The
9 efforts clearly that occur in Europe are
10 not self-regulatory. Dealing with
11 Prop 65 in California is not
12 self-regulatory. But the CIR effort is
13 certainly what the trade association
14 touts as their self-regulatory
15 contribution."

16 Did I read that correctly?

17 MR. WILLIAMS: Actually, it says "being their
18 self-regulatory contribution," your Honor.

19 BY MR. SMITH:

20 Q Is that correct?

21 A I think I said that very well.

22 Q Did you? I thought you said to me under oath in
23 no way is that correct when I asked if it was
24 self-regulatory. I thought that was your response. I
25 can have it read back to you if you would like.

26 MR. WILLIAMS: There's no question pending, your
27 Honor.

28 ///

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1 BY MR. SMITH:

2 Q Do you remember saying that?

3 A I remember answering your question by saying no.

4 Q You don't recall saying any more than that?

5 A I'm lost.

6 Q Okay. We'll move on.

7 The FDA does not require, based on your
8 knowledge and experience, cosmetic companies to share
9 safety information with the FDA; is that correct?

10 A Does not require? No. FDA, according to the
11 Food, Drug, and Cosmetic Act, except for color additives,
12 does not require safety data to be submitted.

13 Q And the FDA cannot require a recall of a
14 cosmetic; is that correct?

15 MR. WILLIAMS: Your Honor, that's beyond the
16 scope.

17 THE COURT: Sustained.

18 BY MR. SMITH:

19 Q Do you have general knowledge about the FDA and
20 what they can and cannot do regarding cosmetics based on
21 what your testimony was on direct?

22 MR. WILLIAMS: Asked and answered, your Honor.

23 THE COURT: Overruled.

24 BY MR. SMITH:

25 Q Doctor?

26 A Yes, I think I do.

27 Q And do you know whether or not the FDA, based on
28 your knowledge and experience at the FDA, can require a

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1 recall of a cosmetic product?

2 MR. WILLIAMS: That's the same question. Beyond
3 the scope.

4 THE COURT: Sustained.

5 BY MR. SMITH:

6 Q Okay. Let's talk about Dr. Andersen for a
7 second, because I haven't had the pleasure of meeting
8 you.

9 Have you ever seen or treated Mrs. Echeverria?

10 A No, I have not.

11 Q Besides the CIR that you've talked about with
12 defense counsel, have you ever lectured, publicate -- had
13 any publications or studies on talc and ovarian cancer?

14 A Yes.

15 Q On talc and ovarian cancer both together besides
16 the CIR?

17 A Oh, I'm sorry. Did you put that caveat of
18 besides the CIR?

19 Q Yes, sir.

20 A I'm sorry.

21 No, I have not.

22 Q And while you were at the FDA, did you have any
23 epidemiological data that you reviewed that dealt with
24 talc?

25 A No, I didn't.

26 Q You're not an epidemiologist?

27 A No, I'm not.

28 Q You're not a toxicologist?

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1 A Not by training.

2 Q What does that mean? What does "not by
3 training" mean?

4 A My responsibilities as a regulatory scientist,
5 as a member of FDA senior executive service, was to be
6 knowledgeable about all of the kinds of data:
7 laboratory, animal, included toxicology, clinical
8 studies. And while I'm not an epidemiologist, frankly, I
9 was responsible for factoring in what's the impact of the
10 findings from epidemiology studies. That's what a senior
11 FDA official does.

12 Q And as a senior FDA official, you would be
13 familiar with the regulations regarding warnings on
14 cosmetics; correct?

15 A I'm aware of the FDA requirements for warnings
16 on products in general.

17 Q What are they?

18 MR. WILLIAMS: Your Honor, objection. That's
19 beyond the scope.

20 THE COURT: Sustained.

21 BY MR. SMITH:

22 Q All right. You talked about toxicology not by
23 trade. The jury has heard from one of my experts,
24 Dr. Laura Plunkett. It's the first witness I brought.
25 She's a toxicologist. She testified about what she had
26 to do to be a certified toxicologist.

27 MR. WILLIAMS: Objection to the preamble, your
28 Honor. It's not a question.

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1 THE COURT: Sustained.

2 MR. WILLIAMS: It's argumentative.

3 BY MR. SMITH:

4 Q Let me ask you this: Have you gone through the
5 certification as a toxicologist under the American Board
6 of Toxicology?

7 A No. I have not, no.

8 Q Are you a paid expert for the defendants in this
9 case?

10 A Yes, I am.

11 Q And what is your hourly rate?

12 A \$695 an hour is what the firm charges for my
13 services.

14 Q And that firm is EAS Consulting Group; correct?

15 A Yes.

16 Q And EA -- excuse me -- that's a
17 tongue-twister -- EAS Consulting Group has a website;
18 correct? You're familiar with that.

19 A Familiar would be extending it. I know that it
20 exists.

21 Q Sure.

22 MR. SMITH: And, Jeff, I'd like to go to P940.
23 It's the website of EAS Consulting.

24 May I publish it, your Honor?

25 THE COURT: Any objection?

26 MR. WILLIAMS: May I have a moment, your Honor?

27 No objection.

28 THE COURT: Go ahead, Counsel.

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1 BY MR. SMITH:

2 Q All right. This is EA -- I can't say it -- EAS
3 Consulting Group. Easy for me to say.

4 And this is where you're a consultant; right?

5 A I'm an independent consultant associated with
6 the EAS Consulting Group.

7 Q Well, the defendants write the checks "EAS
8 Consulting"; right?

9 A I'm sorry?

10 Q Do the defendants that hired you in this case,
11 do they write them to you personally or EAS Consulting
12 Group?

13 A To EAS Consulting.

14 Q Okay. "Specializing in FDA regulatory matters."
15 Do you see that?

16 A Yes.

17 Q Okay.

18 And, Jeff, if we can go down into the gray right
19 here.

20 Can y'all see that? Everybody can see that?

21 "EAS Consulting Group specializes
22 in FDA regulatory matters. Our prime
23 focus is to assist domestic and foreign
24 pharmaceutical, medical device, tobacco,
25 food, dietary supplement, and cosmetic
26 firms comply with applicable laws and
27 regulations."

28 Is that what you understand your consulting

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1 group to do?

2 A Yes.

3 Q Okay. And do you know John Bailey, Dr. Bailey?

4 A Yes, I do know Dr. Bailey.

5 Q Do you know him personally and professionally or
6 just professionally?

7 A It's hard not to be both.

8 Q Okay.

9 I'd like to go to another part of the website,
10 your Honor. It's P943.

11 And there he is -- I've printed this off the EAS
12 site -- John Bailey, Ph.D. And he is an independent
13 adviser, colors and cosmetics.

14 He was formerly at the FDA, was he not?

15 MR. WILLIAMS: Objection. Relevance. Beyond
16 the scope.

17 MR. SMITH: He said he knew him personally and
18 professionally, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Do you know whether or not Dr. Bailey worked at
22 the FDA?

23 MR. WILLIAMS: Relevance, your Honor.

24 THE COURT: Sustained.

25 BY MR. SMITH:

26 Q Regardless, John Bailey works at EAS Consulting;
27 correct?

28 A That's my understanding.

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1 Q Was Mr. Bailey at the FDA while you were there?

2 MR. WILLIAMS: Relevance, your Honor.

3 THE COURT: Let me see counsel at sidebar.

4 (The following proceedings were had
5 at the sidebar out of the hearing of the
6 jury:)

7 THE COURT: What's your offer of proof as to the
8 relevance?

9 MR. SMITH: He talks about the FDA later on.
10 I'm going to set up that Mr. Bailey was the one that
11 responded to the citizen's petition, and he also went to
12 work for the PCPC when he was working for CIR. That's
13 all I'm setting up. He used to be a former employee of
14 the FDA. It says it on his bio.

15 MR. WILLIAMS: Your Honor, clearly beyond the
16 scope.

17 Secondly, Dr. Bailey did not write the response.
18 The response came from someone else at FDA to the citizen
19 petition.

20 Third, this whole line of questioning, almost
21 90 percent of what counsel has done is on the area that
22 is not relevant and beyond the scope of the direct. And
23 he's making me have to object over and over and over
24 again, knowing -- knowing that the Court has ruled that
25 this is not appropriate.

26 So it is a total side issue. He shouldn't be
27 permitted to just talk about John Bailey and try to
28 testify to facts that are outside the record through this

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1 witness.

2 MR. SMITH: Your Honor, the witness is from the
3 FDA where this guy used to work. I mean, if I'm going to
4 tie it up later -- and this guy also went to work with
5 PCPC. He is the one that went to meetings with Johnson &
6 Johnson and meetings on the citizen's petition with the
7 federal government. Now, I'll -- how am I -- I
8 believe -- I think John Bailey worked with him at FDA.

9 THE COURT: Why is that relevant -- why is his
10 knowledge of John Bailey relevant to anything as an
11 expert witness in this case on the stand?

12 MR. SMITH: I think it goes to the relevance of
13 the citizen's petition, to which he has intimate
14 knowledge of the FDA's ruling and of the PCPC.

15 THE COURT: The objection is sustained.

16 (The following proceedings were
17 held in open court in the presence of
18 the jury:)

19 BY MR. SMITH:

20 Q Okay. We were at the EAS Consulting Group
21 website. And I finally said it right.

22 I want to go to a different part of that
23 website. It's P942. It's partnerships and affiliates of
24 the consulting group of which you're a consultant.

25 MR. SMITH: Permission to publish 942, your
26 Honor.

27 THE COURT: Any objection?

28 MR. WILLIAMS: May I just have a moment, your

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1 Honor?

2 No objection.

3 BY MR. SMITH:

4 Q This is partnerships and affiliates of EAS
5 Consulting Group.

6 And if we could go to the second page, Jeff.
7 You see this -- can you blow that up.

8 Consumer Healthcare Products Association, CHPA.
9 It's a -- Consumer Healthcare Products Association,
10 that's affiliated with the EAS Consulting Group for which
11 you're a consultant.

12 Do you see that?

13 MR. WILLIAMS: Lacks foundation, your Honor.

14 THE COURT: The question is does he see it.
15 Overruled.

16 BY MR. SMITH:

17 Q Do you see that, Doctor?

18 A Yes. It's on the screen.

19 Q Did you know that Johnson & Johnson employees
20 are on the board of director of the CHPA?

21 A No, I --

22 MR. WILLIAMS: Assumes facts. "Did you know"?

23 THE COURT: Sustained.

24 BY MR. SMITH:

25 Q Well, let's go to it. It's P938.

26 MR. SMITH: Your Honor, I'd like to publish the
27 CHPA board of directors and other directors.

28 MR. WILLIAMS: Your Honor, relevance.

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1 MR. SMITH: Goes to --

2 MR. WILLIAMS: And lacks foundation.

3 MR. SMITH: Your Honor, they're -- Johnson &
4 Johnson is affiliated with this company he's a consultant
5 with. I think it's highly relevant.

6 It's on page 4 of 76 and 6 of 76 in that
7 document.

8 MR. WILLIAMS: Same objection, your Honor.

9 THE COURT: Overruled.

10 MR. SMITH: Thank you.

11 Jeff, can we go to P938.

12 BY MR. SMITH:

13 Q Here's the CHPA for which the consulting firm
14 that you work for, EAS Consulting Group, which you are a
15 consultant for, is affiliated with the CHPA that we just
16 saw.

17 Do you remember that?

18 A Yes.

19 Q And here's the board of directors for 2016 and
20 '17.

21 If we can go to page 4 of whatever, Jeff. I
22 can't remember now. 4 of something.

23 And it says "Board of Directors."

24 There's Kathleen M. Widmer, J&J Consumer Inc.,
25 McNeil Consumer Healthcare division.

26 Did you realize that J&J Consumer Inc. is a
27 defendant in this case?

28 A Yes, I guess I did.

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1 Q Do you know Kathleen Widmer?

2 A No, I don't.

3 MR. SMITH: Can we go to page 6 of whatever
4 page, Jeff.

5 BY MR. SMITH:

6 Q And it has Educational Foundation Board of
7 Directors.

8 Joy-Lee Pasqualoni -- if I can't say EAS; I'm
9 probably not going to be able to say that -- Johnson &
10 Johnson Consumer Inc. Is J&J Consumer Inc. a defendant
11 in this case?

12 A Yes. What I don't know is what the CHPA
13 Educational Foundation is.

14 Q But, regardless, the consulting group for which
15 you're a consultant is affiliated with the CHPA where
16 Johnson & Johnson sits on whatever board of directors
17 that I just showed you for 2016 and '17; correct?

18 A The CHPA Educational Foundation, yes.

19 Q Okay.

20 Next, I would like to go to your CV. You
21 issued -- you have a CV, which is just your resume in
22 this case; is that correct?

23 A Yes.

24 Q And if we could go to that.

25 MR. SMITH: It's D5, Jeff.

26 Permission to publish his CV, your Honor.

27 THE COURT: Any objection?

28 MR. WILLIAMS: No objection.

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1 MR. SMITH: I think it's right in here, Jeff. I
2 think it's '93 to 2013, I think.

3 BY MR. SMITH:

4 Q '93 to 2013. So that's 20 years, if my math is
5 right.

6 A That's correct.

7 Q "Director of Cosmetic Ingredient Review." And
8 that's the CIR that we've been talking about; right?

9 A Yes.

10 Q "Recruited to head the Cosmetic Ingredient
11 Review, Food & Drug Administration. Established in 1976,
12 the then Cosmetic Toiletry and Fragrance Association" --
13 that's known as the CTFA; right?

14 A Yes.

15 Q Now the Personal Care Products Council -- which
16 is now known as the PCPC or can be called the PCPC;
17 correct?

18 A Yes.

19 Q Okay.

20 "CIR is a unique endeavor by the
21 industry to have the safety of
22 ingredients used in cosmetics thoroughly
23 reviewed and assessed in an open,
24 unbiased, and expert manner."

25 And then it talks about what the director does.
26 And that was you; correct?

27 A Yes.

28 Q I want to talk about the CIR for a minute.

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1 Thank you, Jeff.

2 In your deposition -- and I wrote this down; and
3 correct me if I'm wrong -- you said the interaction
4 between the CIR and the industry group, the PCPC, you
5 would only go kicking and screaming regarding the
6 interaction between the two and that basically the CIR
7 was completely independent from the PCPC and industry and
8 you took pride in that.

9 Do you recall saying something to that effect?

10 MR. WILLIAMS: Objection to the extent it
11 misstates the testimony.

12 MR. SMITH: I can get the testimony if we need
13 it. I just thought we could short-circuit --

14 THE COURT: I don't have the testimony, so I
15 can't rule on the objection.

16 MR. WILLIAMS: I'll withdraw it, your Honor.

17 BY MR. SMITH:

18 Q Do you recall saying something to that effect?
19 And I can pull --

20 A That sounds like the way I would have responded
21 to that kind of question.

22 Q And the CIR was created in 1976; is that
23 correct?

24 A Yes, it was.

25 Q And, like you said in your CV, so that cosmetic
26 companies could substantiate their safety -- right? -- in
27 part?

28 A Well, no.

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1 Q Okay. So the CIR does not rule on the safety of
2 cosmetics?

3 A It does. It is the word "substantiate" that I'm
4 having a problem with.

5 Q All right. Well, maybe I'm not saying --

6 A CIR reviews and assesses the safety of
7 ingredients used in cosmetics.

8 Q Okay. So the CIR was created in 1976; right?

9 A Yes.

10 Q And it reviews the safety of cosmetics?

11 A Yes.

12 Q Okay. Now, so that the jury gets a kind of a --
13 what we're talking about here, the PCPC -- so if I say
14 "PCPC," it was formerly known as the CTFA. So if I say
15 "PCPC," can we have that kind of definition that they
16 were also known as the CTFA prior?

17 A It would help immensely.

18 Q Okay. Thanks. I don't want to say all those
19 acronyms.

20 But the PCPC totally funds the CIR; correct?

21 A Yes, it does.

22 Q And Johnson & Johnson and their supplier of
23 talc, Imerys, formed a Talc Interested Party Task Force
24 for talc issues at the PCPC. We talked about it in your
25 deposition. Do you not recall that?

26 A No, I don't. I think I may have been aware that
27 such a group existed, but that would have been it.

28 Q Let me go to my red binder here.

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1 MR. SMITH: Your Honor, permission to read his
2 sworn deposition testimony, page 195 to, I think, line
3 16 -- 1 through 16.

4 MR. WILLIAMS: May I have the lines, your Honor?

5 THE COURT: 1 through 16, page 195.

6 MR. WILLIAMS: On 195?

7 Not proper impeachment, your Honor. He says he
8 doesn't know what it was.

9 THE COURT: Overruled. Go ahead.

10 BY MR. SMITH:

11 Q Okay.

12 "Question: Do you know what the
13 Talc Interested Party Talc Force is?"

14 And your answer was:

15 "Answer: Not really."

16 And the question was:

17 "Question: You never heard of
18 that?

19 And your answer:

20 "Answer: Oh, I've heard of it. I
21 just -- you asked do I know what it is.

22 "Question: You've heard of it. Do
23 you know what it was about? Do you know
24 anything about it?

25 There was an objection to form.

26 And you answered:

27 "Answer: I guess in a broad sense
28 I'm aware that the industry trade

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1 association would gather particular
2 members who had an ax to grind on a
3 particular issue and bring them together
4 to talk about that issue. I think that
5 was the genesis of the interested party
6 piece of the description. What they
7 really did, I don't have a clue."

8 Do you recall saying that?

9 A It sounds exactly like how I would have said it.

10 Q So the Talc Interested Party Task Force that the
11 two defendants formed under the PCPC had an ax to grind
12 on talc-related issues?

13 MR. WILLIAMS: Assumes facts and lacks
14 foundation.

15 THE COURT: Sustained.

16 BY MR. SMITH:

17 Q Those were your words, were they not?

18 MR. WILLIAMS: Same objection, your Honor.

19 THE COURT: Sustained.

20 BY MR. SMITH:

21 Q Did I just read your testimony correctly?

22 A Yes, you did.

23 Q Thank you.

24 THE COURT: Counsel, may I ask you to do the
25 following for the benefit of the court reporter: When
26 you read deposition testimony, just slow down a little
27 bit.

28 MR. SMITH: I've been accused of that. I get a

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1 little fired up, your Honor. I will slow down.

2 THE COURT: Question, answer; question, answer.

3 MR. SMITH: Sure. I apologize.

4 BY MR. SMITH:

5 Q Sir, I want to -- let's do this.

6 Doctor, I'm going to -- these jurors can't see
7 it. I'm going to kind of tilt it back and forth, if
8 that's okay.

9 A Works for me.

10 Q All right. So we got the CTFA. I did this in
11 opening statement for the jury, but I want to remind
12 them.

13 So we have the CTFA -- can you see that?

14 A Yes.

15 Q The CTFA. And it's now called the PCPC. And
16 that's the trade organization for which these defendants
17 are members of; right?

18 A Trade association.

19 Q Trade association; correct?

20 A That's correct.

21 Q And they pay dues, these defendants as well as
22 other people that are members -- other cosmetic companies
23 that are members of the PCPC, they pay dues, do they not?

24 A That's my understanding.

25 Q And it's your understanding of the PCPC that
26 they pay annual dues based on the size of the company or
27 their income? It's a proportional payment system?

28 A I'm not privy to the details, but I think what I

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1 had heard is that it's -- neither of the two things you
2 said were specific. It related to sales.

3 Q Okay. To sales?

4 A Yeah.

5 Q Do you know if Johnson & Johnson does a lot of
6 sales?

7 A I haven't got a clue.

8 Q Okay.

9 A I apologize -- that is my fallback position of
10 sometimes answering questions.

11 No, I don't know.

12 Q Is Johnson & Johnson, in your opinion, a
13 mom-and-pop organization?

14 A Boy, I'm not sure I know how to answer that
15 question. It was at its inception.

16 Q Sir, I'm --

17 A I'm just --

18 Q This is 2017. I'm not talking about 1893.

19 A Yeah. I think it's fair to say that J&J is a
20 large collection of healthcare and consumer products
21 companies.

22 Q And under the CTFA, these defendants, with their
23 supplier, Imerys, formed the Talc Interested Party Task
24 Force that we just went over in your deposition
25 testimony.

26 Do you recall that?

27 MR. WILLIAMS: Your Honor, that lacks foundation
28 with this witness.

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1 THE COURT: Sustained.

2 BY MR. SMITH:

3 Q You were aware of a Talc Interested Party Task
4 Force, as testified to in your deposition that we just
5 read; correct?

6 A I knew it existed.

7 Q Okay. And so money is paid here by those
8 defendants, just like we talked about?

9 MR. WILLIAMS: Excuse me, your Honor. Objection
10 to the form of the question. Counsel is drawing and
11 essentially testifying without eliciting testimony from
12 the witness. It's improper. It assumes facts not in
13 evidence.

14 MR. SMITH: It is cross-examination, your Honor.
15 I'm just trying to set up a question.

16 THE COURT: I appreciate that.

17 Go ahead, Counsel.

18 MR. SMITH: Thank you.

19 THE COURT: Keeping in mind what the witness
20 said about what he does and doesn't know.

21 MR. SMITH: Yes, your Honor. Thank you.

22 BY MR. SMITH:

23 Q So CTFA, PCPC, Talc Interested Party Task Force,
24 and then the CIR was created. And it's funded solely by
25 the PCPC; right?

26 A If you could back up just a second. On your
27 chart, you put something in parentheses.

28 Q Defendants and Imerys --

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1 A And I have no idea what that --

2 Q I'm sorry. That's just meant to be defendants.

3 A Ahh, that's delta.

4 Q Yes. I'm sorry.

5 A Ahh, okay.

6 Q Okay.

7 MR. WILLIAMS: Pardon me.

8 Thank you, your Honor.

9 BY MR. SMITH:

10 Q CIR funds, solely funds -- is solely funded by
11 the PCPC; right? Is that correct?

12 A Your --

13 Q I'm sorry?

14 A Your podium is blocking me from seeing the --

15 Q Okay. Let me ask you this.

16 THE COURT: Counsel --

17 BY MR. SMITH:

18 Q Does the CIR --

19 A Okay.

20 Q Is the CIR funded solely by the PCPC?

21 A That's my understanding, yes.

22 Q And then the CIR reviews cosmetics from
23 companies from the CTFA, or PCPC, for safety; correct?

24 A Yes.

25 Q Okay. Forgive my writing. Okay.

26 MR. WILLIAMS: Could I just ask -- at least ask
27 counsel to say what he's writing so I don't have to keep
28 walking? If he can say the words, that would be really

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1 helpful.

2 MR. SMITH: Sure.

3 I state -- I have an arrow pointing to PCPC and
4 state that the CIR reviews cosmetics for safety of the
5 PCPC. That's what I said.

6 MR. WILLIAMS: Thank you.

7 BY MR. SMITH:

8 Q Is all that right?

9 A It's "Reviews" --

10 Q "Reviews cosmetics for safety from the PCPC."

11 A I don't understand the "from the PCPC." We
12 review ingredients for safety. I'm not sure what the
13 "from the PCPC" means.

14 Q Okay. Let me clarify.

15 Reviews cosmetics for safety for companies that
16 are members of the PCPC.

17 A Ahh. Okay. The ingredients that are reviewed
18 for safety, I guess, must be manufactured by somebody,
19 and many of them are members of the PCPC.

20 But as the process works, there really isn't
21 that link. The PCPC funds it. The Cosmetic Ingredient
22 Review expert panel is -- has the sole discretion in
23 picking which ingredients are going to be reviewed.

24 So it's that "for the PCPC" that I'm having
25 trouble with.

26 Q I'm trying to --

27 A If it is monetary, if that's what you are
28 referring to, yes, all the money comes from PCPC.

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1 Q Okay. And they review cosmetics from companies
2 that are in the PCPC for safety; is that correct?

3 If I'm a member of the PCPC and I'm a cosmetic
4 company, does the CIR review my cosmetics for safety?

5 A It reviews the ingredients used in your
6 cosmetics for safety.

7 Q Thank you.

8 Okay. In your CV, you stated that you worked at
9 the -- as director at CIR -- was it 20 years, '93 to
10 2013?

11 A That's correct.

12 Q How much were you paid a year?

13 A I don't keep that kind of information in my
14 head.

15 Q How about this. In your deposition, you said
16 approximately \$300,000 a year. Does that sound about
17 right?

18 A Yeah, that's a good ballpark to hear.

19 Q So for about 20 years the PCPC members paid your
20 salary?

21 A That's correct.

22 Q And the PCPC members, one of them that pays dues
23 according to sales is the defendants --

24 A Okay.

25 Q -- correct?

26 A That cascade of logic is correct.

27 Q And I'm not a mathematician, but 20 years times
28 \$300,000 equals -- is it 6 million?

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1 A Boy, I wish that I had made 300K a year for
2 20 years.

3 Q Hold on. Hold on. I just asked you what you
4 made as director, and you said -- you said in your
5 deposition it was \$300,000 a year.

6 A That's correct.

7 Q Is 300,000 times 20 years \$6 million? is my
8 question.

9 A Well, that's certainly true.

10 Q Paid for by members of the PCPC and their dues
11 to the PCPC; is that correct?

12 A I'm just trying -- I don't think there was any
13 other source of funding for the PCPC. So the answer is
14 yes.

15 Q And we talked about the kicking and screaming in
16 your deposition testimony, you used that word about the
17 fierce independence between industry, the PCPC, and the
18 CIR. Do you recall that?

19 A Yes.

20 Q Okay.

21 A It was part of our way of doing business.

22 Q Okay. Well, let's go to -- let me ask you this
23 about that independence. The PCPC office in Washington,
24 D.C., is it in the same -- on the same street -- or
25 excuse me, in the same city, on the same street, in the
26 same building, on the same floor, and on the same suite
27 as the PCPC?

28 A Are you talking about when I was there or

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1 currently?

2 Q I'm talking about currently. The CIR and the
3 PCPC, are they in the same city, the same --

4 A I can short-circuit you. You don't have to go
5 through it again.

6 I've never been there, but my understanding is
7 they share the same offices.

8 Q Same suite?

9 A That's what I said.

10 Q Okay. And you talked to defense counsel about
11 the track record of the CIR for the past -- since 1976 --
12 41 years? '76, is that -- 2017, is that 41 years?

13 A It's approaching 41 years, yes.

14 Q 41 years.

15 A Celebrated the 40th anniversary last fall.

16 Q Congratulations. 41 years, PCPC reviewing
17 cosmetics.

18 You said approximately 5,000 have been reviewed
19 in that time period; correct?

20 A Yes.

21 Q And a whopping 13 were unsafe; right?

22 MR. WILLIAMS: That's argumentative as phrased,
23 your Honor.

24 BY MR. SMITH:

25 Q Were 13 unsafe during that time period?

26 A That's the current status, yes.

27 Q That's 1/5 of 1 percent of the cosmetics that
28 you reviewed in that 41-year period; correct?

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1 A I'll trust your math.

2 Q Okay. I saw a quote from you in -- is it 2012
3 or '13? I can't remember.

4 MR. WILLIAMS: Objection. Assumes facts, your
5 Honor. Improper form.

6 MR. SMITH: I'm just trying to set up the
7 question.

8 THE COURT: Let's just ask the question.

9 BY MR. SMITH:

10 Q Have you said that the CIR annual budget is "not
11 a matter of public record"?

12 A I believe I have said that, yes.

13 Q Why is it not a matter of public record?

14 A Because it's not a matter of public record.

15 Q Why not?

16 A I -- I'm not sure I know how to answer that.

17 Q Can you tell me what the annual budget was the
18 last year you left for the CIR?

19 A No.

20 Q Why not?

21 A I just don't remember.

22 Q Well, you were director for 20 years, sir. You
23 can't tell me what the budget was when you were there in
24 your last year? What was that? How long ago was that?
25 That's four years ago. You can't give me an
26 approximation?

27 A No, I can't.

28 Q So I can't ask you a question so this jury knows

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1 how much -- the totality of the money that the cosmetic
2 companies contribute to the PCPC and how that money is
3 divvied out and where?

4 MR. WILLIAMS: Argumentative.

5 THE COURT: Overruled.

6 You can answer the question, sir.

7 BY MR. SMITH:

8 Q It is not a matter of public record; correct?

9 A It relies on me remembering what that budget
10 was, and I just -- it's not a piece of information that
11 really sticks in my mind. The -- and the explanation for
12 that is that the funding was always adequate to do what
13 the CIR wanted to do. It wasn't a situation where we had
14 to even justify what the budget was going to be for the
15 coming year.

16 The plan for CIR was to do the scientific
17 review, to have the four meetings a year, to prepare all
18 the review materials for the panel to look at, and the
19 industry funded that. So the issue of what was the
20 funding level just wasn't an issue I ever had to really
21 deal with. Whatever we needed, they provided.

22 Q I have --

23 MR. WILLIAMS: Your Honor, if I may, could I
24 just ask counsel to say what he just was writing on the
25 board when Dr. Andersen was speaking?

26 MR. SMITH: I just put his name at the top of
27 that.

28 MR. WILLIAMS: Thank you.

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1 THE WITNESS: Spell it correctly, please.

2 MR. SMITH: Oh. How about that. Is that okay?

3 THE WITNESS: That's better. Thank you.

4 BY MR. SMITH:

5 Q I have no doubt that you were provided what you
6 needed. My question was, do you know what that budget
7 was? Can you tell the jury what the budget was the last
8 year you were there?

9 A I had already answered that. No, I can't. It
10 just -- that budget figure never had a place in my memory
11 chips.

12 Q When you retired after 20 years from the CIR,
13 did you get a retirement package?

14 A I'm not sure what you mean by retirement
15 package. There was a retirement plan that I worked
16 under, and it provided a benefit, yearly benefit on
17 retirement.

18 Q What is that?

19 A Well, I think it's -- I'm not even sure --
20 93,000 a year.

21 Q For how long?

22 A Until I die.

23 Q So while you are here giving testimony about the
24 safety of the defendants' products in front of this jury,
25 you are paid six million dollars partly by funds from
26 Johnson & Johnson, and you are getting a retirement
27 package of \$93,000 a year as we currently sit here based
28 off of that work with the PCPC.

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1 MR. WILLIAMS: Argumentative as phrased.

2 THE COURT: Overruled.

3 THE WITNESS: Yes, I get that retirement
4 benefit.

5 BY MR. SMITH:

6 Q Let's talk about the CIR on talc. Okay? Is
7 that okay? Sir?

8 A Yes.

9 Q Okay. The CIR did not conduct any independent
10 studies itself when it assessed the study of talc;
11 correct?

12 A No, it didn't.

13 Q Okay. So it gathered information that was in
14 the public domain, brought it together with the process
15 you talked about with defense counsel, and arrived at the
16 opinion that you gave, the CIR gave; correct?

17 A That's correct.

18 Q Okay. And the CIR published its final report,
19 review of talc that you have gone over with defense
20 counsel, in 2013; is that right?

21 A That's correct.

22 Q And so that's four years ago.

23 When did the literature search in years stop
24 that went into the 2013 CIR report? Do you remember?

25 A I believe it was 2012.

26 Q 2012. Okay. So five years ago is when the
27 literature stopped that went into the assessment of the
28 CIR on talc; right?

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1 A Yes.

2 Q Okay. Industry provided input to the CIR on
3 talc and wrote letters to you both -- well, wrote letters
4 to you with this input; correct?

5 A Yes.

6 Q And I would like to go over some of those
7 letters that you went over in your deposition that are to
8 you.

9 And I would like to first post EE572.

10 MR. WILLIAMS: Objection, your Honor. It
11 appears to be a draft, if I'm looking at the right one.

12 THE COURT: Yeah. I don't have EE572 in my
13 book, I don't think, Mr. Smith. I have a series of P
14 exhibits, no E exhibits. And in another book I have D
15 exhibits, P exhibits, but no E exhibits.

16 MR. SMITH: Do you have it, Doctor?

17 THE COURT: I don't have it, Counsel.

18 THE WITNESS: I don't know where I would look.

19 MR. SMITH: Look in your notebook.

20 Can I approach, your Honor?

21 THE COURT: Yes.

22 MR. SMITH: I'm sorry. Let's get on the same
23 page. It's here, your Honor. Just look at 572. See,
24 here are the tabs, right here.

25 THE WITNESS: I see it. You can't see the
26 letters.

27 MR. SMITH: Yeah. The letters are blocked,
28 that's the problem.

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1 Do you see 572, your Honor?

2 THE COURT: Got it.

3 MR. SMITH: Okay. Thank you.

4 THE COURT: This is a --

5 MR. SMITH: Can I ask the witness?

6 THE COURT: Yeah.

7 BY MR. SMITH:

8 Q Doctor, you have 572 in front of you?

9 A I do.

10 Q And you discussed this in your deposition, did
11 you not? Do you remember being questioned about it?

12 MR. WILLIAMS: Objection. May we be heard?

13 THE COURT: Yes.

14 If you all want to stand up and stretch for a
15 second, please go ahead.

16 (The following proceedings were had
17 at the sidebar out of the hearing of the
18 jury:)

19 MR. WILLIAMS: Your Honor, my objection is,
20 number one, counsel doesn't have a good faith basis to
21 put this in front of the witness. It's a draft letter
22 that the witness testified to in deposition that he had
23 no idea, had never seen before. So for him to pull this,
24 it is an internal Imerys document, a draft, with the
25 Imerys Bates number on it.

26 So, again, it is a question designed to make us
27 have to object, knowing that we will object in front of
28 the jury when counsel has no bases for asking this

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1 witness about it.

2 The purpose of the deposition is to ask whether
3 a witness has knowledge. The witness said he didn't have
4 knowledge. Counsel knows he doesn't have knowledge.

5 It is improper, and we would ask that he not be
6 permitted to do it with any document at this time.

7 MR. SMITH: If counsel would let -- wait to
8 object until I have laid a foundation and then -- I was
9 then going to ask him has he received it.

10 THE COURT: Is the answer to the question going
11 to be yes?

12 MR. SMITH: I don't know.

13 MR. WILLIAMS: He does know, your Honor, because
14 on page 224 of the deposition he was asked does this
15 appear to be a form letter that would be addressed to you
16 on the PCPC or list others.

17 MR. SMITH: Okay. I'll move on.

18 MR. WILLIAMS: The answer was "I have no idea."

19 MR. SMITH: I'll move on.

20 MR. WILLIAMS: Can I have a lavatory break?

21 THE COURT: Yes.

22 MR. WILLIAMS: Thank you.

23 (The following proceedings were
24 held in open court in the presence of
25 the jury:)

26 THE COURT: Folks, we've been going almost an
27 hour and a half. Why don't we take our morning recess,
28 take ten minutes or so, and then come back.

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1 The usual admonitions will apply, "admonition"
2 being the fancy word for warning.

3 (Recess taken 10:59 A.M. to 11:15 A.M.)

4 THE COURT: Back on the record with all counsel
5 here, Dr. Andersen on the stand, all jurors and both
6 alternates here. Thank you.

7 Mr. Smith.

8 MR. SMITH: May I proceed, your Honor?

9 THE COURT: You may.

10 MR. SMITH: Thank you.

11 BY MR. SMITH:

12 Q Okay, Doctor, we have about 40 minutes to lunch.
13 I've got a few more questions. Is that okay?

14 A Yes.

15 Q Thank you.

16 We were talking about, before we left for the
17 break, that you said that industry provided input into
18 the CIR on talc, and they actually wrote letters to you
19 with this input.

20 You agreed with me. Do you recall that?

21 A Yes.

22 Q Okay. And so you received letters from
23 different industry groups while at the CIR on talc during
24 the literature review; correct? The SLR?

25 A During the literature --

26 Q Don't you call it a systematic literature
27 review, SLR?

28 A Scientific literature review.

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1 Q Excuse me. Scientific literature review?

2 A When that was completed and published, it had a
3 60-day comment period, and, yes, we got comments back
4 from industry.

5 Q And so you received letters to that effect.

6 Doctor, I would like you to look at P571. I
7 mean, excuse me, EE571.

8 A Ahh.

9 Q Sorry. I can't see the letters either.
10 Are you with me?

11 A Okay. Can I see that?

12 Q Is that a letter to you?

13 A No.

14 MR. WILLIAMS: EE571, your Honor.

15 BY MR. SMITH:

16 Q Are you Dr. F. Alan Andersen?

17 A Yes.

18 Q It's April 4th, 2009. You don't see that? Are
19 we on the same page? It's a letter from the CRE.

20 A I'm sorry. I was still on 572. I apologize.

21 Q That's all right.

22 A Yes, now I do see that. That is -- yes, I do
23 see it.

24 Q You received it? It's entitled -- addressed to
25 you; correct?

26 A Yes.

27 MR. SMITH: Permission to publish EE571, your
28 Honor.

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1 MR. WILLIAMS: May I have one moment, your
2 Honor?

3 THE COURT: Yes.

4 MR. WILLIAMS: No objection.

5 MR. SMITH: Jeff, can you put up EE571? Can you
6 blow that up, Jeff?

7 BY MR. SMITH:

8 Q This is a letter from Center for Regulatory
9 Effectiveness, Bill Kelly, and it's dated August 4, 2009,
10 to you. And it says right here, "Dr. Andersen" -- well,
11 it's to you at the CIR. Do you see that?

12 A Yes.

13 "Dr. Andersen, as promised quite
14 some time ago, I'm hereby providing you
15 with a copy of the talc bibliography
16 that I've been assembling for some time
17 in the hopes that it might prove useful
18 in the CIR review."

19 You received this from the CRE; correct?

20 A Yes.

21 Q Do you know who the CRE is?

22 A As the process went on, we kind of figured out
23 what it was. When this first came in, I don't think we
24 had a sense of what it was.

25 So, yes, I understand that it is -- appears to
26 be largely an industry advocacy group.

27 Q Did you have any knowledge that the CRE was
28 hired by the PCPC regarding talc-related issues?

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1 A I didn't know that. Wouldn't have cared.

2 Q Okay.

3 MR. SMITH: Go back up to the top, Jeff.

4 MR. WILLIAMS: I'm sorry, your Honor. It was a
5 little late. Objection. Assumes facts on the last and
6 misstates prior testimony. Not from this witness, but --

7 MR. SMITH: I just asked him a question, your
8 Honor.

9 MR. WILLIAMS: Testimony from the previous
10 witness.

11 MR. SMITH: He said he didn't know.

12 THE COURT: He didn't know. Overruled.

13 MR. SMITH: May I proceed?

14 MR. WILLIAMS: Thank you, your Honor.

15 MR. SMITH: May I proceed, your Honor?

16 THE COURT: Yes.

17 MR. SMITH: Thank you.

18 BY MR. SMITH:

19 Q Bill Kelly wrote you this from the CRE; is that
20 correct?

21 A That's correct.

22 Q And you understand that he was an attorney for
23 the CRE?

24 A No. I didn't link him with the word "attorney."

25 Q Okay. But he wrote you on behalf of the CRE;
26 correct?

27 A That's correct. That's what the letterhead
28 says.

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1 Q Next, I would like to go to 567, Doctor. EE567.

2 A Okay. Yes, I have that.

3 Q Is this a letter to you -- a second letter to
4 you from the CRE?

5 A I have no idea if it's the second letter or not.

6 Q Is it a --

7 A It is another letter from the CRE.

8 Q Is it the second letter we've gone over today
9 from the CRE?

10 A Yes.

11 Q How about that? Is that okay?

12 A Yes.

13 Q Okay. Is it from -- let's go to it, Jeff.

14 MR. SMITH: Permission to publish 567, your
15 Honor.

16 MR. WILLIAMS: May I have one moment, your
17 Honor? It's a lengthy document.

18 No objection.

19 MR. SMITH: Can we pull it up, Jeff?

20 MR. WILLIAMS: Your Honor, no objection to the
21 letter itself. The attachments we may have issues.

22 BY MR. SMITH:

23 Q Well, Doctor, let me ask this: You received
24 this letter with attachments; correct? I mean --

25 A Yes.

26 Q Okay.

27 A At least I hope the attachments were included,
28 but yes.

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1 MR. SMITH: If we can blow up the top again,
2 Jeff.

3 BY MR. SMITH:

4 Q And this is Center for Regulatory Effectiveness.
5 Do you see that, Doctor?

6 A Yes.

7 Q And that's the CRE we are talking about?

8 A Yes, it is.

9 Q And then right here -- what's the date on that,
10 Jeff, 2012?

11 A Yes.

12 Q And if we can go right here, that's you; right?
13 Dr. F. Alan Andersen?

14 A That's correct.

15 MR. SMITH: And if we can go below that, Jeff,
16 right here.

17 BY MR. SMITH:

18 Q Initial Comments on CIR draft Scientific
19 Literature Review."

20 We talked about that, SLR. We used those terms
21 earlier?

22 A That's correct.

23 Q "For 'Talc as Used in Cosmetics' (posted by CIR
24 August 22nd, 2012).

25 It says in the first line here:

26 "Dear Dr. Andersen, we commend CIR
27 staff for the thoroughness of the draft
28 SLR. We do have a number of comments

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1 aimed at improving the evaluation."

2 And then he goes on for some comments.

3 MR. SMITH: And then, Jeff, if we could go to
4 page 19. It is 19 at the bottom.

5 BY MR. SMITH:

6 Q And then he says, "Respectfully, William G.
7 Kelly, Jr."

8 He doesn't have a doctor in front of his name,
9 does he?

10 A No.

11 Q "Center For Regulatory Effectiveness."

12 Do you see that?

13 A Yes.

14 Q And then he has some attachments. And I would
15 like to go to one of those. It's --

16 THE COURT: Let's not publish the attachments
17 until you indicate what they are, please.

18 BY MR. SMITH:

19 Q Okay. I would like to go to trial Exhibit
20 567-00029. It's a newspaper article regarding talcum
21 powder and ovarian cancer.

22 Do you have it in front of you, Doctor?

23 A Yes.

24 Q Are you familiar with this document?

25 A No, not particularly.

26 Q Are you familiar with this study since you did a
27 systematic review of the literature regarding talc and
28 ovarian cancer?

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1 MR. WILLIAMS: Objection. Vague and ambiguous.

2 THE COURT: Sustained.

3 BY MR. SMITH:

4 Q Are you familiar with the epidemiological
5 studies regarding talc and ovarian cancer and the basis
6 of your opinion here today?

7 A Yes. We reviewed the epidemiology studies. We
8 did not review newspaper articles.

9 Q Okay. Well, this is a 1982 publication, is it
10 not?

11 A No. It's not a publication; it's a newspaper
12 article.

13 Q Publication/newspaper article. Okay? Is it
14 1982? Is it dated 1982?

15 A Yes, it's dated 1982.

16 Q Was there a study published by Dr. Cramer in
17 1982, an epidemiological study from Harvard, that you
18 reviewed?

19 A Yes. I'm aware of the Cramer publication on his
20 epi study.

21 Q And you said you received these attachments to
22 this letter. It's addressed to you; correct?

23 A That's correct.

24 MR. SMITH: Your Honor, permission to publish
25 the article.

26 THE COURT: Any objection?

27 MR. WILLIAMS: Yes, we do have an objection.
28 It's hearsay. We would ask for an offer of proof.

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1 THE COURT: Offer the proof, Counsel, at
2 sidebar.

3 MR. SMITH: Well, I can maybe clear it up with
4 one question.

5 BY MR. SMITH:

6 Q Do you have any reason to believe that the
7 Baltimore Sun is not a reliable authority?

8 MR. WILLIAMS: Vague and ambiguous. Reliable
9 authority for what?

10 THE COURT: Sustained.

11 MR. SMITH: I'll move on.

12 BY MR. SMITH:

13 Q Are you aware of a study in 1982, Doctor, that
14 showed an increased risk of ovarian cancer from genital
15 talc use that was published by Dr. Cramer?

16 A I remember the Cramer epidemiology study. I'd
17 have to look at it to see exactly what it said about the
18 odds ratios that they found.

19 Q You don't remember that the first
20 epidemiological study done in the United States in 1982
21 by Dr. Cramer did or did not show an increased risk of
22 ovarian cancer from genital talc use and whether or not
23 it was statistically significant?

24 MR. WILLIAMS: Objection. Misstates the
25 testimony. Argumentative.

26 THE COURT: Overruled.

27 BY MR. SMITH:

28 Q You are not aware of that?

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1 A I'm aware of the Cramer study, but it remains
2 the case that the effort that the CIR expert panel did
3 was to look at all the available data. And, in this
4 case, there is no particular premise given to the first.
5 So I -- no, the first one doesn't strike me as being
6 anything. There's a whole bunch of them, and we had to
7 look at them all.

8 Q I'm not saying you didn't have to look at them
9 all; I'm just saying, based on your review -- you said
10 you looked at the epidemiological data for this case in
11 rendering your opinions; correct?

12 A That's correct.

13 Q And you can't remember whether or not the first
14 epidemiological study ever done on genital talc use and
15 ovarian cancer by the authors at Harvard, Dr. Cramer,
16 showed a statistical significant increased risk of
17 ovarian cancer from genital talc use?

18 A I'm telling you exactly that.

19 Q Okay. All right. Let's go to the next
20 document. It is E573. And if you'll flip over to the
21 second page of that, that's what I wanted to ask you
22 about. It's an email to you.

23 A This is EE573?

24 Q Yes, sir.

25 A Got it.

26 Q And if you can flip over to the second page of
27 that, it's an email exchange. Do you see down at the
28 bottom?

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1 A I'm sorry. Second page.

2 Q Yes, sir. Look down at the bottom. It's an
3 email to you.

4 A Yes, I see that.

5 Q Okay.

6 MR. SMITH: Permission to publish that portion
7 of EE573, your Honor.

8 MR. WILLIAMS: Your Honor, no objection to
9 pages 2, 3, and 4.

10 THE COURT: All right. Go ahead.

11 MR. WILLIAMS: No objection to 2, 3, and 4.

12 MR. SMITH: And, Jeff, if we can just blow this
13 up all down here.

14 BY MR. SMITH:

15 Q And this is, again, from Bill Kelly that we
16 talked about earlier from the CRE; correct?

17 A At least -- yes, the first part of it is the
18 email to me.

19 Q And it has to do with the CIR talc review. And
20 you're Alan Andersen; correct?

21 A Yes.

22 Q And it says:

23 "Dear Dr. Andersen: I know you are
24 very busy preparing for the September
25 meeting, but the talc producers and
26 users had several questions, which, if
27 possible, they would like answers to as
28 soon as possible because they have an

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1 annual meeting in San Diego next
2 Thursday. They are also highly engaged
3 in conversations on how to participate
4 in the review."

5 THE COURT: Counsel.

6 BY MR. SMITH:

7 Q Did you receive this email from the CRE, Bill
8 Kelly?

9 THE COURT: Counsel, I think you inadvertently
10 misread the last sentence.

11 MR. SMITH: I'm sorry. I apologize.

12 THE COURT: Just slow down a little here.

13 BY MR. SMITH:

14 Q Okay.

15 "They are also actively engaged in
16 conversations on how to participate in
17 the review."

18 THE COURT: Thank you.

19 MR. SMITH: I apologize.

20 THE WITNESS: Yes. I got that email.

21 BY MR. SMITH:

22 Q Okay. And I have several more here. And I
23 don't want to go waste the jury's time. But you did
24 receive similar emails, similar letters from other
25 industry groups regarding the SLR -- is that correct? --
26 or comments to it?

27 MR. WILLIAMS: I'm sorry. Just vague and
28 ambiguous as to the term "similar."

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1 THE COURT: Do you understand the question?

2 THE WITNESS: Yeah, I think I do.

3 Regarding the SLR, the factual answer is no, we
4 didn't. This is regarding preparations for the first
5 meeting at which CIR is going to talk about draft
6 reports. I'm nitpicking, but, yes, we received lots of
7 input from industry. This one related to scheduling.

8 BY MR. SMITH:

9 Q Okay.

10 A Other pieces of input related to -- one we just
11 looked at, the 19-page letter, had technical comments in
12 it. So we've gotten lots -- we had gotten lots of input.

13 Q Okay.

14 A I still say it as if I own it.

15 Q So you had a lot of input from industry
16 regarding the CIR, as we originally talked about?

17 A Well, a lot -- we got input from industry.

18 Q Okay.

19 A Not as much as we have in other cases and more
20 than in others.

21 Q Okay. I would like to go -- you discussed with
22 defense counsel the CIR on talc which came out, your
23 review; correct?

24 A I'm sorry. Say again.

25 Q The CIR on talc --

26 A Yes.

27 Q -- you reviewed; correct? You received it? I
28 mean, you talked about it with defense counsel?

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1 A Oh, yes. Sorry.

2 MR. SMITH: Your Honor, permission to publish
3 274, P274.

4 MR. WILLIAMS: No objection, your Honor.

5 THE COURT: Go ahead.

6 MR. SMITH: Thank you.

7 And, Jeff, could we pull that up, please.

8 MR. WILLIAMS: For the record, your Honor, may I
9 say that that's the same as D368.

10 THE COURT: All right. Thank you.

11 MR. SMITH: If we could go to -- Jeff, if we
12 could go to page 58 of 64. And could we go to the
13 funding section down here.

14 BY MR. SMITH:

15 Q This is the CIR final published review of talc;
16 correct?

17 A Final published review.

18 Q Yes. And it says here:

19 "The authors disclosed receipt of
20 the following financial support for the
21 research, author" --

22 Excuse me. I don't have my glasses.

23 MR. WILLIAMS: Your Honor, for the record, I
24 misspoke. This is the same as Exhibit L384.

25 THE COURT: This is the final published?

26 MR. WILLIAMS: The final final, yes.

27 THE WITNESS: The final final.

28 ///

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1 BY MR. SMITH:

2 Q Okay.

3 -- "research, authorship, and
4 publication of this article. The
5 articles in this supplement were
6 sponsored by the Cosmetic Ingredient
7 Review."

8 The Cosmetic Ingredient Review is financially
9 supported by the PCPC; is that correct?

10 A That's correct.

11 Q And earlier with defense counsel you went
12 over -- it was the expert panel -- you recall that --
13 actually, you said you sat in the room when we were in
14 the meetings but actually did the voting for talc in this
15 review?

16 A That's correct.

17 Q Okay.

18 A Procedures called for the expert panel members
19 to do the voting.

20 MR. SMITH: And I have a different number for
21 it, Mr. Williams -- it's P959 -- but it's the same
22 demonstrative that we used.

23 MR. WILLIAMS: No objection, your Honor.

24 MR. SMITH: Jeff, can you pull up 959.

25 BY MR. SMITH:

26 Q All right. This is the review panel for talc;
27 correct?

28 A That's correct.

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1 Q Expert review panel?

2 A Yes.

3 Q Who did you say Wilma Bergfeld was?

4 A She's professor of dermatology and head of the
5 dermatopathology unit at the Cleveland Clinic Foundation.

6 Q And who is Donald V. Belsito?

7 A Don is -- I don't think I said it yesterday,
8 but, because I actually know, he's the Len Harber
9 Professor of Dermatology at Columbia University.

10 Q Okay.

11 A I remember that because I knew Len Harber.

12 Q Okay. And I was looking at some publications of
13 Wilma Bergfeld. What did you say her role was now
14 regarding the Cosmetic Ingredient Review and talc?

15 A Wilma was the chair of the expert panel.

16 Q So she was the chair.

17 Give me one second, Doctor.

18 And I saw a publication of -- or she was --
19 first of all, do you know if Dr. Bergfeld regularly gives
20 talks and presents at, for instance, the American Academy
21 of Dermatology? Are you familiar with that?

22 A Yes.

23 Q Okay. And the American Academy of Dermatology,
24 that's a reputable outfit; correct?

25 A In my view.

26 Q Okay.

27 MR. SMITH: Your Honor, permission to publish

28 958 -- P958.

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1 MR. WILLIAMS: 958 is not in my notebook.

2 MR. SMITH: It's in the second notebook. I'm

3 sorry. Hold on.

4 THE WITNESS: I have -57 and -59.

5 MR. SMITH: Hold on.

6 May I approach, your Honor?

7 THE COURT: Yes.

8 MR. SMITH: Here you go, your Honor. You have
9 it?

10 THE COURT: I do.

11 MR. SMITH: Permission to publish P958.

12 MR. WILLIAMS: Lacks foundation to the witness,
13 your Honor.

14 MR. SMITH: Your Honor, he is familiar with the
15 American Academy of Dermatology and that Dr. Bergfeld
16 would give talks.

17 THE COURT: Lay a foundation before you publish
18 this.

19 MR. SMITH: Okay.

20 BY MR. SMITH:

21 Q Let me ask you this, Doctor: Any of the expert
22 panel review, do you check them for conflicts of
23 interest?

24 A That's correct.

25 Q And so they should not be receiving payments or
26 an expert or have any type of disclosure of a conflict of
27 interest with industry; correct?

28 A The cosmetics industry, yes.

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1 Q And did you check that, or did they voluntarily
2 do that?

3 A They provide that information to me.

4 Q Do you double-check it?

5 A No, I don't really.

6 Q Okay. To the best of your knowledge, did any of
7 the expert panel review on talc and ovarian cancer have
8 any conflicts of interest?

9 A No.

10 MR. SMITH: Permission to publish 958, your
11 Honor.

12 MR. WILLIAMS: Still lacks foundation to the
13 witness.

14 THE COURT: It does, and I don't know what the
15 date of it is, what year it is.

16 MR. SMITH: Your Honor, to be honest with you,
17 whether it's before or after, I think it has the same
18 effect.

19 THE COURT: I disagree with that, Counsel. Lay
20 a foundation for this. If you don't have a foundation,
21 you may not publish it.

22 BY MR. SMITH:

23 Q Well, do you have any reason to believe that the
24 American Academy of Dermatology is not a reliable or
25 authoritative source of information?

26 MR. WILLIAMS: Objection, your Honor. Lacks
27 foundation to the witness. Plus irrelevant for this
28 purpose and no foundation for the witness.

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1 THE COURT: Overruled.

2 MR. SMITH: Thank you.

3 BY MR. SMITH:

4 Q Do you have any reason to doubt that they are an
5 authoritative, reliable source of information?

6 A No, I don't.

7 MR. SMITH: Permission to publish P958, your
8 Honor.

9 MR. WILLIAMS: Same objection. Relevance hasn't
10 been laid, your Honor.

11 THE COURT: Sustained.

12 BY MR. SMITH:

13 Q If any of the expert panel for the talc and
14 ovarian cancer for the CIR had any conflict of interest
15 of working for the defendants or receiving money for the
16 defendants, is that information that you would know
17 today?

18 A Yes. That would be information that the -- in
19 my role as director of CIR I would want to have.

20 MR. SMITH: Permission to publish 958, your
21 Honor.

22 MR. WILLIAMS: Lacks foundation, your Honor.

23 THE COURT: Sustained.

24 BY MR. SMITH:

25 Q Okay. Let's go to Donald Belsito. He was on
26 the -- Belsito; correct?

27 A Belsito, yes.

28 Q Belsito. Do you know whether he was receiving

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1 any payments from the defendants during the time period
2 that he was sitting on the expert panel for the CIR
3 review for the safety of talc?

4 A Any payments --

5 Q Yes.

6 A Boy, I would have to go back -- I don't have
7 access to. All of the scientists on the panel on
8 occasion, like Dr. Bergfeld, would give scientific
9 presentations. And those scientific presentations often
10 were sponsored by industry. So could Don have made a
11 presentation on his work and been supported by industry?
12 Yes, it's possible.

13 He would have told me about that, and I would
14 have given a thumbs-up or thumbs-down to each of the
15 circumstances, as I had done for Dr. Bergfeld.

16 Q So you're saying you gave a thumbs-up for
17 Dr. Bergfeld? Is that what you just said?

18 A Yes. The -- if you would focus on -- I don't
19 know. Can we put that P958 back up.

20 Q Your counsel didn't want it to be shown.

21 MR. WILLIAMS: First of all, I'm not his
22 counsel, your Honor. Second of all, that's an improper
23 statement by counsel.

24 THE COURT: It is improper, but --

25 MR. SMITH: Excuse me.

26 BY MR. SMITH:

27 Q I was not allowed to show the document, Doctor.
28 So I want to ask you.

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1 A Oh, I thought you did. I'm sorry.

2 Q I was trying to.

3 My question is, so you recall now giving
4 Dr. Bergfeld a thumbs-up regarding a conflict of interest
5 that she had during the CIR review of talc with the
6 defendants Johnson & Johnson?

7 A As the conduct of CIR business, every seminar
8 that a CIR member gave that involved industry sponsorship
9 or was to an industry group was brought to me and cleared
10 as to whether this actually presented a conflict of
11 interest. There's no question that the support existed.
12 If you are going to Johnson & Johnson to give a seminar,
13 there's no question it's Johnson & Johnson, but the
14 question of whether this represented a conflict of
15 interest, in my view, it didn't.

16 Q Okay. So you were aware that Dr. Bergfeld, the
17 leader of the CIR on the expert panel that had a vote on
18 whether talc was safe or not, you had knowledge had a
19 conflict of interest of receiving money from Johnson &
20 Johnson during the time that she's reviewing it and you
21 said, in your judgment, thumbs-up?

22 MR. WILLIAMS: Misstates testimony, your Honor.

23 MR. SMITH: I think it's pretty accurate.

24 THE WITNESS: No, it's not accurate. I said it
25 did not represent a conflict of interest.

26 BY MR. SMITH:

27 Q Correct. Thumbs-up?

28 A She went to talk about her research on alopecia,

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1 hair loss in women. That's her major area of research.
2 I did not consider that a conflict of interest with the
3 CIR's review of cosmetic ingredients. She was giving a
4 medical paper.

5 Q Sir, the lead expert panelist, you had knowledge
6 of, was receiving money from the defendants who -- one of
7 their major products is at issue in the CIR review, and
8 you did not -- is it disclosed anywhere in this review?

9 A I'm sorry. Is -- is what disclosed? The fact
10 that she received that money?

11 Q Yes, sir.

12 A No, it's not.

13 Q Right. And I'd like to go to 274 to go to the
14 conflicts of interest -- excuse me -- declaration of
15 conflicts of interest.

16 MR. SMITH: Can we go to 274, Jeff.

17 It has been previously put before the jury, your
18 Honor.

19 MR. WILLIAMS: Is it P274?

20 MR. SMITH: Yes.

21 THE COURT: P274, that's the final CIR report.

22 MR. WILLIAMS: Thank you.

23 MR. SMITH: Get my glasses on so I can see what
24 all is going on.

25 All right. Let's go to the declaration of
26 conflicts of interest, Jeff.

27 BY MR. SMITH:

28 Q Okay.

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1 "The authors declare no potential
2 conflicts of interest with respect to
3 research, authorship, and publication of
4 this article."

5 A That's correct.

6 Q So there's no mention -- so if this goes out to
7 the general public, we come into court in front of a
8 jury, or any other scientist in the world looks at this
9 paper, they do not know that the lead expert panelist
10 reviewing the safety of talc was receiving money from
11 Johnson & Johnson during the time that this publication
12 is being authored; correct?

13 A I don't know about the part of your statement
14 relating to "during the period of time." But I will
15 acknowledge that the existence of financial support for
16 her medical research existed, and I didn't consider that
17 a conflict of interest with the work being done by CIR.
18 And that's how it was captured in the declaration.

19 Q You didn't consider it a conflict of interest,
20 according to Dr. Andersen, who's on the payroll for
21 \$300,000 a year, determined that --

22 A It was my --

23 Q -- being funded by them?

24 A -- responsibility to make that determination,
25 yes.

26 Q Did you run it by anybody?

27 MR. WILLIAMS: Objection, your Honor.
28 Argumentative. I really think it's inappropriate.

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1 THE COURT: It's compound. Which question would
2 you like him to answer?

3 MR. SMITH: Yes, your Honor.

4 BY MR. SMITH:

5 Q Did you run it by anybody?

6 A No. I was the director of the Cosmetic
7 Ingredient Review.

8 Q You got paid \$300,000 a year partly by these
9 defendants that had the conflict of interest with the
10 head expert panel reviewer?

11 MR. WILLIAMS: Argumentative. Assumes facts.

12 THE COURT: Overruled.

13 THE WITNESS: My determination was that there
14 wasn't a conflict of interest.

15 BY MR. SMITH:

16 Q Okay. Do you think that's information that a
17 scientist, me, the jury, or anybody that's going to look
18 at this paper and not understand all that's going on give
19 to decide what weight I want to give this, don't you
20 think that's important information to put in the
21 declaration of the conflicts of interest?

22 A No.

23 Q Okay. All right. What about Dr. Donald
24 Belasito? You said you were aware that he was doing some
25 talks during this time.

26 And can we pull up that expert panel again,
27 Jeff. What is it? P -- Jeff, it's P959.

28 All right. So we talked about the lead -- what

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1 was her title again? The what of the expert panel
2 review?

3 A Wilma Bergfeld was the chair of the CIR expert
4 panel.

5 Q Okay. And I mispronounced the name. Sorry.
6 Donald V. Belsito; is that right?

7 A That's correct.

8 Q Okay. What payments were you aware that
9 Johnson & Johnson was giving him during the time that
10 this expert panel was reviewing the safety of talc for
11 which is the main ingredient in baby powder?

12 MR. WILLIAMS: Lacks foundation and assumes
13 facts, your Honor.

14 MR. SMITH: He has already talked about that he
15 was aware of it and he didn't determine it was a conflict
16 of interest, your Honor.

17 THE COURT: Overruled.

18 MR. SMITH: Thank you.

19 THE WITNESS: I don't have a recollection of a
20 specific list or item. What I do recall is the standard
21 operating practice, which is, on a regular basis, I got
22 requests from the members of the expert panel, "I want to
23 give this seminar." Many of them were at the Academy of
24 Dermatology meetings and talked about their professional
25 work. And I would either approve it or not approve it.

26 BY MR. SMITH:

27 Q Were you aware of payments, like Ms. Bergfeld --
28 excuse me -- Dr. Bergfeld, Dr. Belsito was receiving from

August 11, 2017

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1 Johnson & Johnson and their subsidiary Janssen Biotech
2 during the time that he sat on review on the CIR for the
3 safety of talc? Did you give that a thumbs-up and
4 thumbs-down like you did for Dr. Bergfeld?

5 A As it would -- again, I don't remember specific
6 details, but, as a pattern, if his medical research was
7 being sponsored, then that was not considered a conflict
8 of interest with his review of cosmetic ingredients.

9 Q According to Dr. Andersen?

10 A That's the way I implemented it, yes.

11 Q Okay.

12 MR. SMITH: Let's go back to -- Jeff, can we go
13 to P274.

14 Your Honor, it's the safety assessment of talc
15 that we've been talking about, the CIR. Can I publish
16 some other parts of that, please?

17 THE COURT: Go ahead.

18 MR. SMITH: Thank you.

19 BY MR. SMITH:

20 Q I want to go -- this is a thick document, and
21 it's got a lot of footnotes to scientific literature
22 that's cited in the body of the paper; correct?

23 A I don't know that there are very many footnotes.

24 Q Well, I counted 218, whatever it is. If you
25 want to say that's not many; it is. It's 218.

26 Do you recall that?

27 A Those are not footnotes. I mean, I don't mean
28 to nitpick, but those are reference citations. I believe

August 11, 2017

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1 there was a couple of footnotes on the first page,
2 numbering four.

3 Q Can we agree there are 218 citations --

4 A Yes.

5 Q -- to scientific literature that's in the body
6 of the CIR?

7 A Yes.

8 Q Okay.

9 I would like to go to -- can we go to page 63 of
10 64, Jeff, and focus in on Number 177.

11 "W.G. Kelly, initial comments on
12 CIR draft scientific literature review
13 for talc. Talc as used in cosmetics
14 posted by CIR, Aug. 22, 2012, letter
15 report submitted to Andersen F.A. by
16 Kelly W.G., 2012."

17 Do you see that?

18 A Yes.

19 MR. SMITH: Then, Jeff, if we can flip over to
20 where that citation references, which is page 33 of 64.
21 And if we can go to that second paragraph, Jeff, right
22 here.

23 BY MR. SMITH:

24 Q Okay.

25 "The possibility that using
26 cosmetic talc powder can cause ovarian
27 cancer was suggested when talc particles
28 were found on human ovarian tissues.

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1 The translocation of talc particles from
2 the perineum to the ovaries would
3 require that these particles pass from
4 the perineum through the vagina and the
5 cervical canal, move across the uterus
6 and against the ciliary motion of the
7 Fallopian tubes across the peritoneal
8 space between the fimbriae and ovaries,
9 escape phagocytosis in the peritoneal
10 space, and attach to the surface of the
11 ovaries to accumulate in the ovaries."

12 And there is the Citation 177; correct?

13 A And 178.

14 Q And 178; right?

15 A Yes, it is.

16 Q We just went through the letters of Bill Kelly
17 from the CRE to have input into the CIR. And he's an
18 attorney for the CRE that you're quoting for this
19 scientific conclusion?

20 MR. WILLIAMS: Assumes facts, your Honor.

21 THE COURT: Sustained.

22 BY MR. SMITH:

23 Q Is this not a scientific -- are these not
24 scientific terms and conclusions here that I just read to
25 you? Are they legal conclusions?

26 A I'm not sure in -- just exactly how to answer
27 your question. The CIR expert panel determined that this
28 information should be included in the report. The

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1 information came from two different sources. And, as
2 part of our process, we make even the unpublished data
3 from the CRE available and part of the package. If the
4 panel concludes that that information is independently
5 verified by itself, then it puts it in. But because it
6 came from a lawyer -- which I don't think they knew --
7 but whether it did or didn't, it's the information that
8 the panel focuses on, not the source.

9 Q The source is a lawyer from the CRE who was
10 hired as a consulting group for the PCPC for which these
11 defendants are a member of; correct?

12 MR. WILLIAMS: Your Honor, assumes facts.

13 THE COURT: Sustained.

14 BY MR. SMITH:

15 Q Do you know that to be true?

16 A Do I know what to --

17 Q The CRE was an industry trade group that -- we
18 discussed earlier --

19 A Yes, that, I know.

20 Q Okay. They're hired by the PCPC?

21 A I don't know that they were hired by the PCPC.
22 That part I guess I don't know.

23 Q Were they consultants for the PCPC?

24 A I really don't know that.

25 Q You don't remember the conversation we had
26 earlier about the CRE and Bill Kelly? We went through
27 the two letters I showed the jury? Do you not recall
28 that?

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1 A I recall looking at a letter from CRE to me
2 and -- giving comments on the SLR. I recall the email
3 from Bill Kelly on procedures and process. I'm just
4 not -- I don't recall anything that told me that he was a
5 consultant or that that group was consulting with PCPC.
6 And I could just be misremembering. I just don't
7 remember that specifically.

8 Q In any event, he's a --

9 A But it's an industry group. There's no
10 question.

11 Q Okay. He consulted for an industry group;
12 right?

13 A Well, CRE is an industry group, yeah.

14 Q Correct. Okay.

15 Well, you're not a consulting company in an
16 industry group if you're not consulting for industry;
17 right?

18 All right. We'll leave it at that.

19 I'll tell you what, Bill Kelly is a lawyer at
20 the CRE who's cited on 177 in the CIR review; correct?

21 A That's correct.

22 MR. WILLIAMS: That's mis- --

23 MR. SMITH: That's all the questions I have at
24 this time -- well, not for this witness, but before
25 lunch, if you want to take a break, your Honor. I'm
26 getting ready to move to another topic.

27 THE COURT: Okay. Maybe this would be a good
28 time for lunch.

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1 Let's take our recess for the noon hour.

2 Everybody leave your notes here. Have a good lunch.

3 Don't discuss the case. Don't do any research. Wait

4 until you hear all the evidence before you form any

5 opinions. Have a nice lunch.

6 (Jury leaves the courtroom.)

7 (The following proceedings were

8 held outside the presence of the jury:)

9 THE COURT: You can step down, sir. Thank you.

10 Is everybody good until 1:30?

11 MR. SMITH: Yes, your Honor.

12 MR. WILLIAMS: Yes.

13 THE COURT: Okay.

14 (Whereupon, the matter was adjourned for

15 lunch at 11:58 A.M. and to be resumed at

16 August 11, 2017, at 1:30 P.M..)

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August 11, 2017

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

3

FOR THE COUNTY OF LOS ANGELES

4

5

DEPARTMENT 307

HON. MAREN E. NELSON, JUDGE

6

7

COORDINATION PROCEEDING,)

SPECIAL TITLE (RULE 3.55))

8

) JCCP NO. 4872

)

9

JOHNSON & JOHNSON TALCUM) REPORTER'S

POWDER CASES,) CERTIFICATE

10

)

11

12

13

14

15

I, Pamela Cotten, CSR NO. 4497, pro tem reporter of
the Superior Court of the State of California, for the
County of Los Angeles, do hereby certify that the
foregoing pages, 3205 - 3329, comprise a full, true and
correct transcript of the proceedings and testimony taken
in the above-entitled cause on August 11, 2017.

21

22

Dated this 11th day of August, 2017.

23

24

25



PAMELA COTTEN, CSR, NO. 4497

26

OFFICIAL PRO TEMPORE REPORTER

27

28

Exhibit 135

**Plaintiff's Exhibit
No.
P-374**

Page 1 of 15



2010 Powder Program Overview

Objective:

- Recruit new and younger users by giving them a compelling reason to use JOHNSON'S® Baby Powder

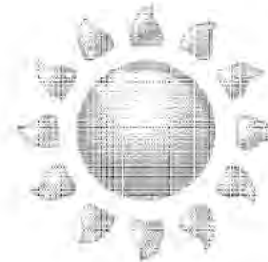
Key Strategies and Tactics:

- Target overweight women living in hot climates during key summer season
 - Launch campaign with an insertion in People Magazine within weight loss edit and use Weight Watchers Magazine and Everyday with Rachael Ray to target women who are overweight
 - Utilize local or geo-targeted media in hot markets that have a high percentage of overweight consumers

Budget: \$555.2M (+12%)

Timing: Q2-Q3

Media Mix: Print: 47%; Radio/Digital: 53%

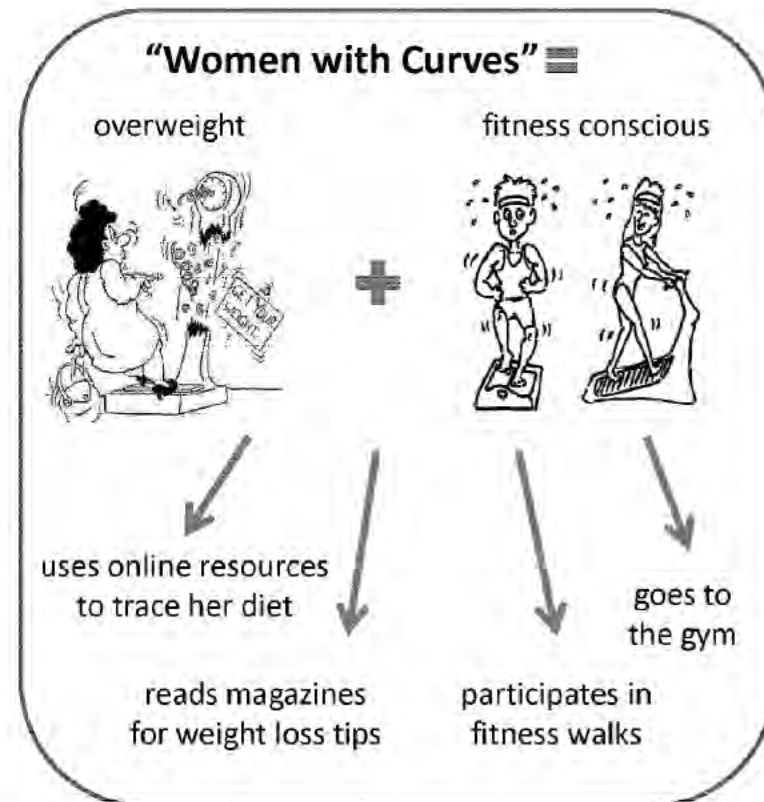




2008/2009 Programs targeted “Women with Curves”

Historic target exhibited distinct behaviors that allowed JOHNSON’S® to reach her easily

- Print in Weight Watchers Magazine
 - Print out-performed norms for Weight Watchers magazine
 - Advertorials explained alternate usages
- Digital on diet sites
 - Digital banners slightly exceeded benchmarks with a .15% CTR
 - Hub on WeightWatchers.com to increase relevance of messaging vs. brand page, resulted in about 24,000 visits
- Sampling at gyms and walking events

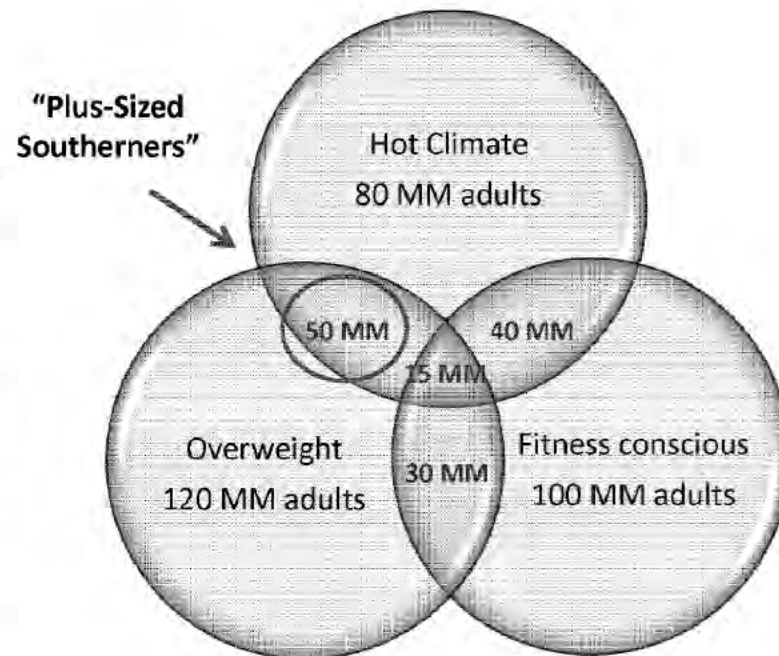




2010: Re-focus target to increase sales opportunity

2010 target is not only the largest population segment, but also the segment that needs powder the most

- Focus on overweight women living in hot climates (aka “Plus-Sized Southerners”) during key summer season
 - Hit consumers in regions with great NEED for powder
- In general, “Plus-Sized Southerners”:
 - Hold a high school diploma
 - Live in cities with large suburban sprawl
 - Have friends with similar body types
- Broader 2010 target doesn’t have unique behaviors that allow us to hyper target in media
 - 2010 targeting approach—Geo-target in large Southern markets





Localized Southern Media Opportunities

Both radio and digital allow JOHNSON'S® to reach the "Plus-Sized Southerners"

Local Promotional Radio *Engaging*

- + 45% of women 18-34 are heavy users
- + Opportunities to create relevant platforms to engage consumers
- + Less stringent copy rules in DJ chatter allows JOHNSON'S® to hint at alternate usages
- More costly on a CPM basis (comparable with print)

Geo-Targeted Digital *Efficient*

- + Low CPMs
- + Large lifestyle hubs assure mass coverage in key local markets
- More difficult to explain usage
- Brand website is outdated

Recommended
Option

Current print plan provides national coverage, but over-indexes in local Southern regions



Digital vs. Radio

While radio delivers fewer impressions, the quality of each impression is greater

	Digital	Promo Radio
Net Cost	\$300M	\$300M
Markets	Dallas, Atlanta, Nashville, Mobile, Jackson	Dallas, Atlanta, Nashville, Mobile, Jackson
Partners	AOL, Everyday Health	TMPG
Length of Campaign	3 months	8 weeks
Total Impressions	16.7MM	7.8MM





Promotional Radio Details

Campaign would run 8 weeks in 5 Southern Markets: Dallas, Atlanta, Nashville, Mobile and Jackson

- Local DJ Brand Ambassadors
- Customized, Brand-Themed Contesting
 - Engage, Motivate & Entertain the Target
- Online extensions on Local Station Websites including DJ Video Blogs
- Radio Station Appearances
 - Leverage In-Store Support & Drive Purchase
 - On-Site DJ Talent, Call-ins, Sampling, etc.





Next Steps

Program Alignment:

Early Feb

Begin TMPG execution:

Early March

Radio Live:

May

Appendix

9

Protected Document--Subject to Protective Order

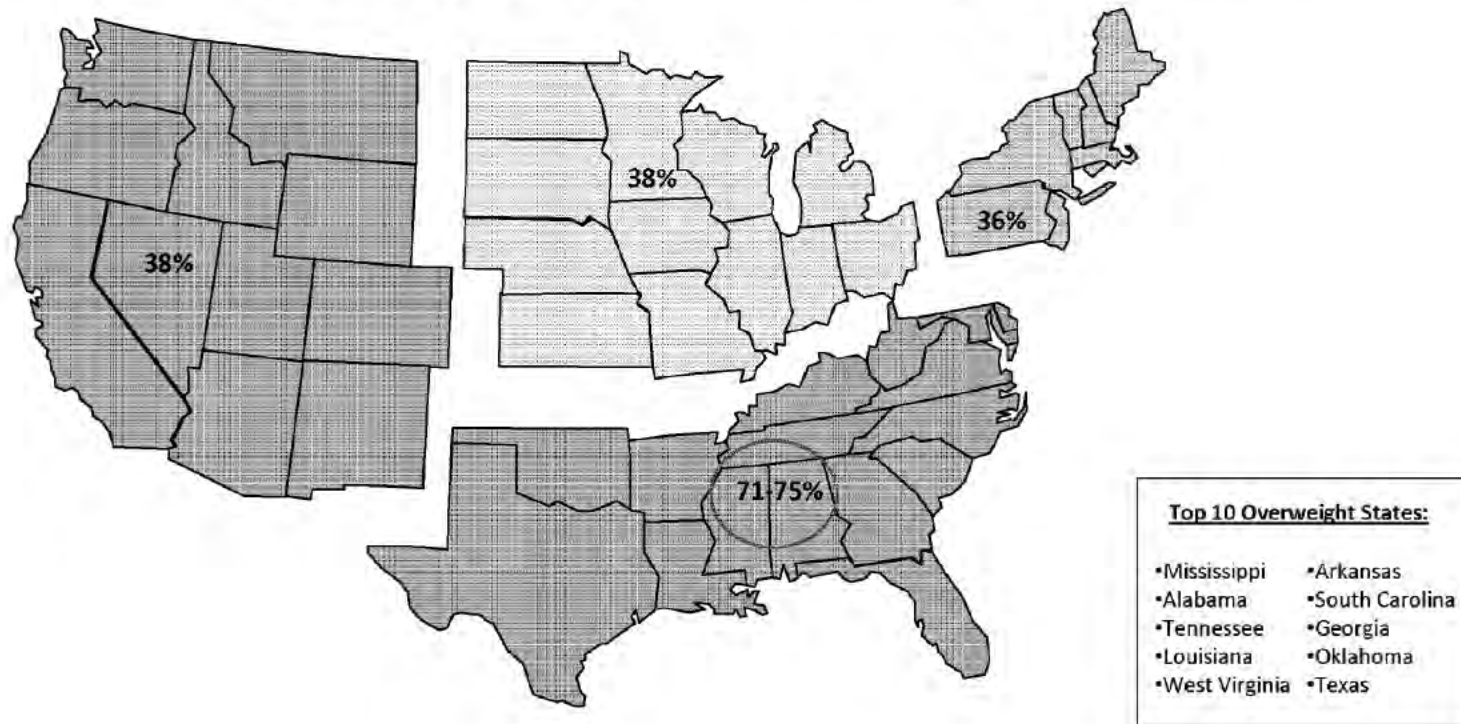
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Program Reach on a Regional Level

Total Powder plan delivers 35.7MM impressions in the Southern Region (hot climates/overweight states)

Map reflects Weight Watchers, People and Promotional Radio distribution



10 Source: MRI Doublebase, 2008

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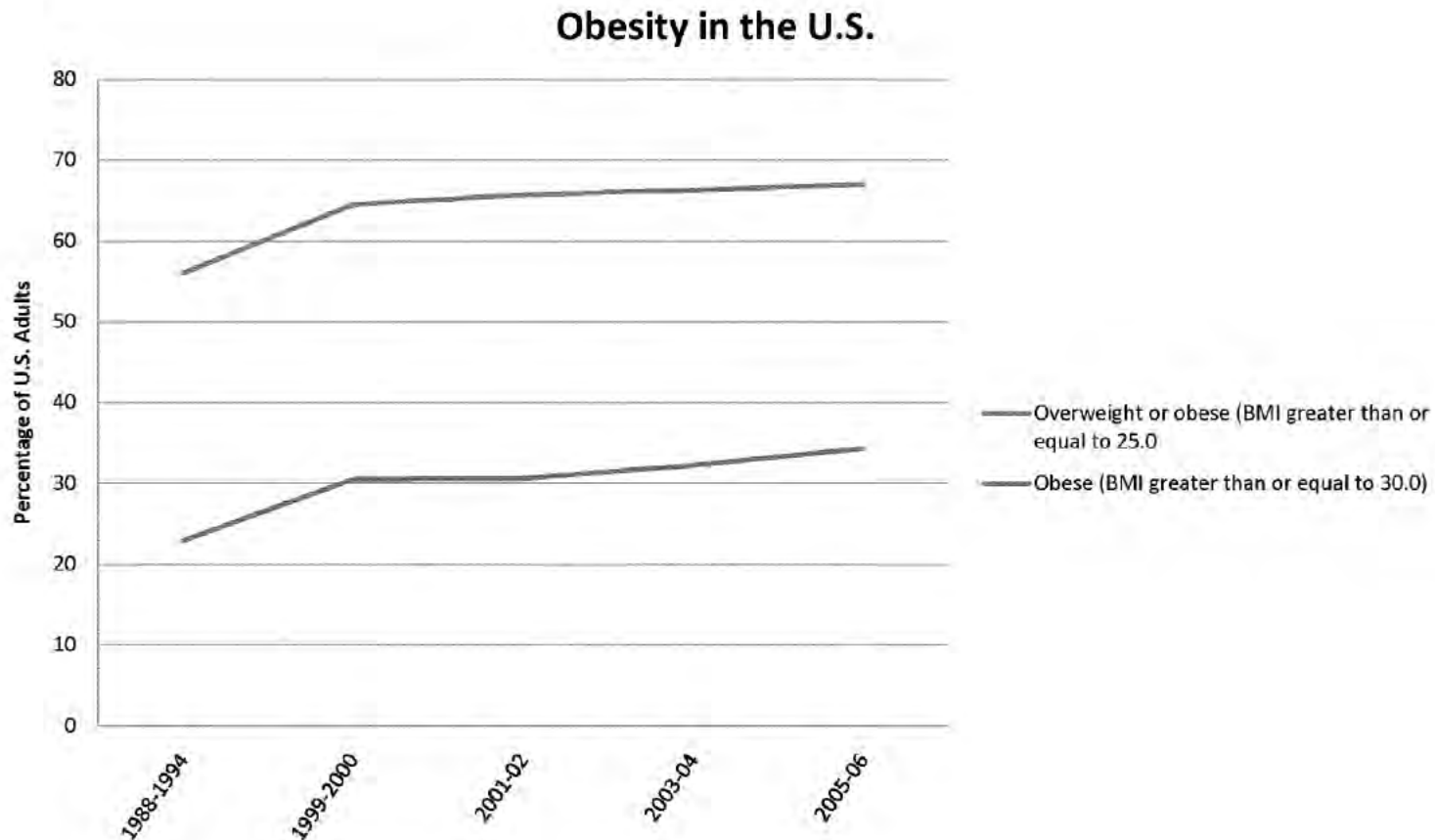
Promotional Radio Components

6-8 week campaign during summer months

- On Air: DJ Brand Ambassadors
 - Local DJs trained as Brand Ambassadors
 - Deliver Influential Endorsements / DJ Chatter
 - Communicate Key Messaging / Positioning
 - Support & Promote Marketing Initiatives
 - Provide Consumers with Valuable Information & Incentives
- Customized, Brand-Themed Contesting
 - Various Entry Mechanisms: Log on, Call-in, Text-in, etc.
 - Engage, Motivate & Entertain the Target
 - Reinforce Key Communications
 - Maximize Participation via Prize Giveaways
 - Prizes Leveraged from Stations & Awarded on Behalf of Brand
- Extensive Online Exposure: Radio Station Websites
 - Brand Logo & Hyperlink
 - Dedicated Contesting Pages
 - E-mail Blasts sent to Opt-in Recipients
- Additional Exposure - where available
 - Streaming Spots
 - Pre-Roll Video
 - Rovion Technology
 - DJ Video Blogs
 - Inclusion / Sponsorship of Station Outbound Text Messages
- In-Market – if desired by the JBP Client: Radio Station Appearances
 - Leverage In-Store Support & Drive Purchase
 - Conduct at Key Accounts, Brand Events, etc.
 - On-Site DJ Talent, Call-ins, Sampling, Cool Prize Giveaways, Station Vehicle, Signage & Activities



Growing obesity rates in US



12 Source: Mintel/National Center for Health Statistics

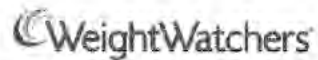
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JNJ 000093567



Spot vs. Promotional Radio

	Spot	Promo
Net Cost	\$294.2M	\$300M
Markets	Dallas, Atlanta, Mobile, Jackson	Dallas, Atlanta, Nashville, Mobile, Jackson
Impressions	7.1MM	7.8MM
GRPs	60/wk	60/wk (1,448 est. spots)
Length of Campaign	8 weeks	8 weeks



2008 & 2009 Weight Watchers Partnership

Objective

- Communicate JOHNSON'S® Baby Powder comfort benefits to "moisture prone" women

Strategy

- Target "Women with Curves" that are working on change through Weight Watchers

Execution

- Surround weight loss success stories across platforms
 - Print: Weight Watchers magazine
 - Online: weightwatchers.com
 - On the ground: Weight Watchers meetings, events and fitness centers

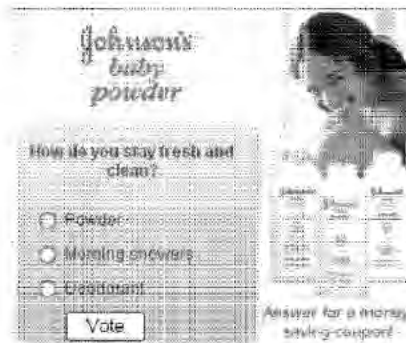
2008 Spend: \$355M

2009 Budget: \$400M (in planning),

\$375M final



Weight Watchers Advertorial



Online Poll Ad-unit

Program Details

- Print advertorials and premium inserts in Weight Watchers magazine with tips for success and coupons
- Online media surrounding success stories, healthy lifestyles and , in-meeting literature distribution, and event and fitness center sampling
- Literature & coupon distribution at Weight Watchers meetings
- Sampling at events and fitness centers

Results

- Print out-performed norms for Weight Watchers magazine
- Digital performance exceeded benchmarks
- Noticeable increase in consumption at both Wal-Mart and Target during the campaign

2009 Enhancements

- Expand digital program to additional relevant sites

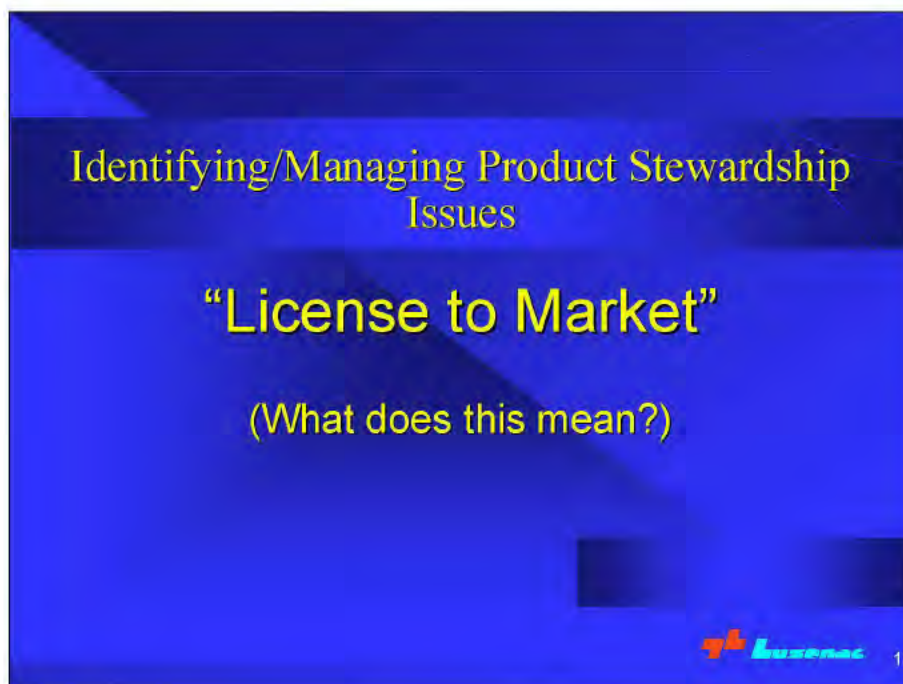


2009 Digital Results on WW.com hub

Although significant visits, overall microsite performance was underwhelming

- # of total visits – 24,385
- # of people that opened/downloaded the calendar with tips: 23
- # of people that clicked on the coupon: 553
- # of people that clicked through to workout tips article: 517
- # of people that clicked “Learn More”: 62
- # of people that clicked “Refresh Daily Routine” article: 704

Exhibit 136



Definition: *License* - to permit, authorize,
allow, certify.....

You want to drive? – You need to learn the rules and obtain a license.

You want to fish? – You need to learn the rules and obtain a license.

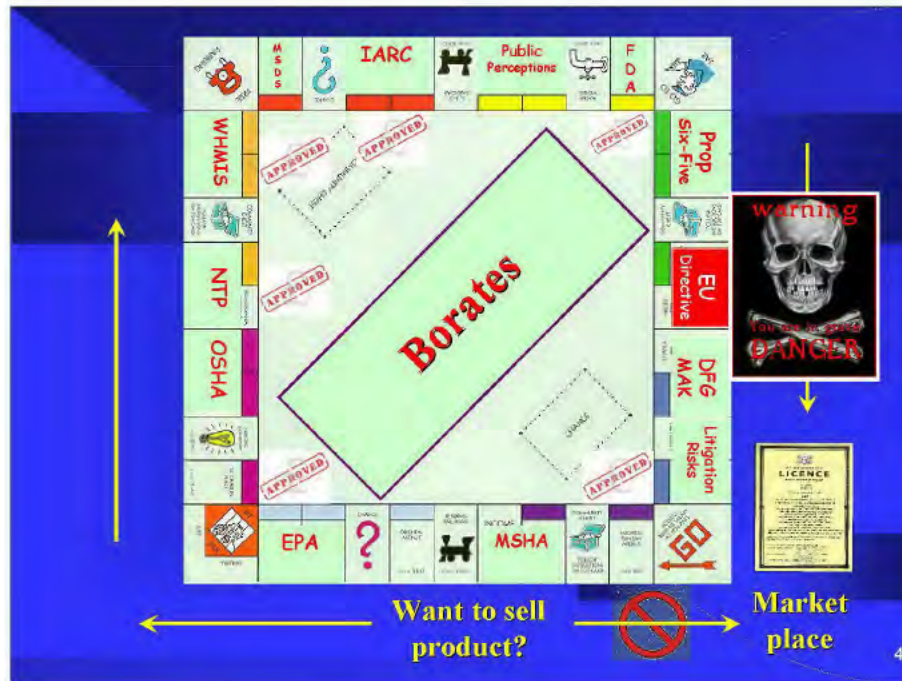
You want to get married? - You need to learn the rules (???) and obtain a license.

You want to market a product? – You need to learn the rules; and while you do not obtain an official marketplace license, a change in the rules can have a material effect on your ability to market your product.



2









**What do we need to do to
protect our license to
market?**

- Retain internal regulatory expert(s)
- Closely (and regularly) monitor regulatory and agency activities
- Utilize Internet tools e.g., “Google News Alerts”
- Establish and maintain ties with outside resources e.g., expert legal counsel, “watchdog” services (Center for Regulatory Effectiveness), medical experts with knowledge of your product, legislators, policy makers

 6

Exhibit 137

[Letter of proposal to FDA and NIEHS/NIH]

The FDA has legislative responsibility for direct regulation of unsafe ingredients in cosmetics under the Food, Drug and Cosmetic Act. In 1994, as a result of concerns regarding the 1993 NTP animal study and recently published epidemiological studies linking talc and ovarian cancer, the FDA and the International Society for Regulatory Toxicology and Pharmacology co-sponsored a workshop to discuss the issues and to see whether they could arrive at any consensus views on how they should be interpreted. Twenty FDA scientists participated, along with numerous scientists from academia, industry, cancer research institutions, NIEHS, NCI, and other organizations.

At the beginning of the workshop, Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors, presented the "Introduction: Overview - Scope of the Workshop", in which he stated:

"... I think it is reasonable to expect by the end of the workshop to have a discussion or even to reach a consensus of the many scientific and medical experts that are participating in and attending this meeting about the relevance of the recent reports to the safety of talc to human health risks."

At the conclusion of the Workshop, an Executive Summary was prepared by the Rapporteur, Dr. Jelleff Carr (Talc: Consumer Uses and Health Perspectives" in *Reg. Tox. Pharm.* 21(2):211-60 (1995). With regard to the ovarian cancer issue, Dr. Carr explains the consensus that was reached:

"Following the many issues raised by all presenters, the ensuing discussion generally agreed that while some weak association between talc exposure and ovarian tumors has been reported, it was not sufficient warning for concern."

"The possibility of an association of talc exposure and ovarian cancer is an important hypothesis of potential public health importance. However, this association remains a research hypothesis whose verification or falsification needs additional study."



“[E]pidemiologic studies have provided weak and conflicting risk signals for this association and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures.”

Indeed, the prediction by the panel that additional epidemiology studies on this subject would prove inadequate to clearly define an association between the perineal application of talcum powder and an increased risk of ovarian cancer was accurate. When NTP began their review of non-asbestiform talc in 2000, eight additional epidemiologic studies were published and evaluated by NTP. The eight additional studies continued to provide weak and conflicting risk signals with no consistent trend by duration or frequency of talc use. Appropriately, the NTP Board of Scientific Counselors Subcommittee concluded that the listing of cosmetic talc was not scientifically justified and voted 7-3 not to list talc (not containing asbestiform fibers).

Since the conclusion of NTP review in 2000, only one additional case-control study has been published (Central Valley of California). Not surprisingly, this additional epidemiological study provided no new information of scientific utility.

Given all this scrutiny during the last decade of “cosmetic talc” and its association with ovarian cancer, Luzenac cannot imagine that an additional review by NTP would result in a reversal of consensus about the scientific validity of this hypothesized association. But given the sensitive nature of this very serious women’s health issue and the lingering suspicions concerning cosmetic talc as a possible risk factor, Luzenac would like to propose a remedy to FDA and NIEHS/NIH that would eliminate the need for any further debate and review of this issue.

We propose:

1. The talc industry in the United States will voluntarily phase-out the production and sale of all cosmetic talc products used specifically for consumer dusting powders, body powders, baby powders, and any other loose powder products that might reasonably be anticipated to be used by women for perineal application.

2. In cooperation with domestic cosmetic and pharmaceutical member companies of the CTFA, this product phase-out will occur within XX months of acceptance of these proposals by NTP and FDA.
3. The voluntary withdrawal would not include such products as medicated foot powders where it would not be reasonably anticipated that the product would be used for perineal dusting; nor would the withdrawal include cosmetic talc products sold for make-up, lipstick, eye-shadow and cream foundations where it would not be reasonably anticipated that the product(s) would be used for perineal dusting.
4. The CTFA will assist the FDA in developing an appropriate cosmetic warning label for any dusting or body powders containing talc which are produced or imported after an established date. The label would warn the consumer the product is not to be used for genital dusting and would report of the possible association between genital dusting and ovarian cancer. The warning label would be mandatory.

The result of these proposed actions would:

1. In very short order, virtually eliminate the exposure potential in the general population to dusting powders containing talc. As more and more dusting powders have already been re-formulated with increased levels of cornstarch, the proposed actions would accelerate these product conversions.
2. Eliminating the perineal exposure potential for women suspends the need for NTP to proceed with a review of cosmetic talc. Given the weakness of the science, it is improbable that a listing recommendation would have resulted – meaning the debate on this theorized association would continue unresolved. These voluntary actions proposed by the talc industry and CTFA member companies would end the debate and allow researchers to focus on other more plausible risk factors.

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Metadata

Author	rzazensk	ORIGINAL
Custodian	Zazenski, Rich;	ORIGINAL
DateCreated	11/30/2004 9:03 PM	ORIGINAL
OtherCustodians	Zazenski, Rich;	ORIGINAL

Exhibit 138

Litigation Issues

- February 26, 2002 -

General Stages of a Civil Complaint – United States

1. SERVICE OF THE COMPLAINT

- I. Engage Counsel Licensed in State
- II. File Formal Response to all Charges with Court

2. DISCOVERY PROCESS

- I. Interrogatories
- II. Request for Documents
- III. Depositions
- IV. Expert Witness Designation & Reports
- V. Request for Admissions
- VI. Pre-trial Conference
- VII. Arbitration/Mediation

3. CIVIL TRIAL

- I. Opening Statements
- II. Case-in-Chief - (Plaintiff presents evidence)
- III. Defense - (Defendant presents evidence)
- IV. Rebuttal - (Plaintiff may have option to call rebuttal witnesses)
- V. Closing Arguments
- VI. Jury Deliberates - Renders Decision

Current Case Status for Luzenac America

- **5** silicosis cases in Texas. In 2 cases, records show sales of Luzenac talc and chlorite to facility where plaintiff alleges exposure.
- **1** asbestos/silica/talc case in New York. Records show sales of Windsor unfloated talc to Bondo (body patch).
- **1** asbestos case in Maryland. Records show sales of Yellowstone talc to facility where plaintiff alleges exposure.
- **1** asbestos case in California. Rio Tinto companies named in suit. No record of talc usage or exposure. Plaintiff has died and case is being re-served as a wrongful death case.

1

Protected Document – Subject to Protective Order

Plaintiff's Exhibit
No.

P-26

LUZ013094

Specific Litigation Issues & Problems

- **Asbestos exposure claims.** Continue to be filed. Jury awards continue to overwhelmingly favor Plaintiffs. Last year, seven Tyler Pipe employees awarded \$10 million. Luzenac America was a defendant in original pleadings.
- **Crystalline silica claims.** Gaining in popularity – becoming the next generation “toxic tort industry” for legal community.
- **Luzenac America corporate history.** Complicates the defense and accountability of claims:
 - a. 1988 – Cyprus purchases assets of the Vermont Talc company
 - b. 1989 – Cyprus purchases stock of Windsor Minerals – Indemnity provisions in Sales Agreement
 - c. 1992 – Rio Tinto purchases the stock of Cyprus Talc Company. Sales agreement requires Luzenac to assume responsibility in 1993 for all product liability claims on Cyprus sales (pre-1992)
 - d. 1997 – Cyprus acquires Amax Gold
 - e. 2000 – Phelps Dodge acquires Cyprus/Amax
- **Multiple ownership changes.** Site closures, personnel changes, etc., have made record and document discoveries extremely difficult. Pre-1992 Cyprus records still under the legal “privileged” umbrella of Cyprus counsel. Fewer and fewer company “historians” available to provide court permitted testimony (in lieu of documentation).
- **“Deep Pockets”.** Traceability to Rio Tinto will put/keep Luzenac on many “radar screens”. Larger settlement demands will be put upon Luzenac for dismissal.
- **R. T. Vanderbilt.** Publicity on N.Y. State talc/tremolite issues continues to reinforce the talc/asbestos association e.g., the “2000 Crayon controversy – Seattle Post Exposé”.
- **NTP Carcinogenic Listing.** Listing of “talc not containing asbestos fibers” could be potentially devastating from a product liability perspective. [*Plaintiffs attorney: “So Mr. Zazenski, please tell the Court when Luzenac first learned that talc was possibly associated with ovarian cancer?” “When did you first start warning consumers that this association was possible and under study”. “Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the women and children in our society?” Etc. etc. etc.*]

Exhibit 139

Video No Image

[https://lanierlawfirm.sharefile.com/
ds8ae050614a248fb8](https://lanierlawfirm.sharefile.com/ds8ae050614a248fb8)

Exhibit 140

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

IN RE:

FOLEY V. AVON PRODUCTS, INC. ET AL.	MID-L-3095-18 AS
FRACE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-600-18 AS
GATMAITAN V. IMERYS TALC AMERICA, ET AL.	MID-L-4252-18 AS
GRABOWSKI V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-6805-16 AS
GREENE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-2456-18 AS
GRIFFIN V. CYPRUS AMAX MINERALS COMPANY, ET AL.	MID-L-4826-18 AS
HODJERA V. BORGWARNER MORSE TEC, LLC, ET AL.	MID-L-5368-17 AS
MCNEILL-GEORGE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-7049-16 AS
SELVAGGIO V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-598-18 AS
WENDOWSKI V. IMERYS TALC AMERICA, INC., ET AL.	MID-L-6635-17 AS

VIDEOTAPE DEPOSITION OF SUSAN NICHOLSON, MD
DAY 2

Transcript of the deposition of the witness,
called for Oral Examination in the above-captioned
matter, said deposition being taken pursuant to
Superior Court Rules of Practice and Procedure by and
before MARC BRODY, a Notary Public and Certified Court
Reporter of the State of New Jersey, at the MIDDLESEX
COUNTY COURTHOUSE, 56 Paterson Street, New Brunswick,
New Jersey, on Wednesday, March 6, 2019, commencing at
approximately 10:00 in the forenoon.

BRODY DEPOSITION SERVICES
235 East Broad Street, Suite 1
Westfield, New Jersey 07090

Phone: 908-789-2000 Fax: 908-789-2007

Brody Deposition Services

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<p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 COHEN, PLACITELLA & ROTH, P C</p> <p>4 127 Maple Avenue</p> <p>5 Red Bank, New Jersey 07701</p> <p>6 732-747-9003</p> <p>7 BY: CHRISTOPHER PLACITELLA, ESQ</p> <p>8 AND: DENNIS GEIER, ESQ</p> <p>9 Attorneys for Plaintiff</p> <p>10</p> <p>11 HAWKINS PARNELL & YOUNG, LLP</p> <p>12 600 Lexington Avenue, 8th floor</p> <p>13 New York, New York 10022</p> <p>14 646-589-7678</p> <p>15 BY: MANUEL A GUEVARA, ESQ</p> <p>16 Attorneys for Defendant, Revlon</p> <p>17</p> <p>18 McGIVNEY, KLUGER & COOK, P C</p> <p>19 18 Columbia Turnpike, 3rd floor</p> <p>20 Florham Park, New Jersey 07932</p> <p>21 973-822-1110</p> <p>22 BY: ELIZABETH BARNA, ESQ</p> <p>23 Attorneys for Defendant, Whittaker, Clark &</p> <p>24 Daniels</p> <p>25</p> <p>26 BLANK ROME, LLP</p> <p>27 One Logan Square</p> <p>28 Philadelphia, Pennsylvania 19103</p> <p>29 215-569-5397</p> <p>30 BY: JAMES T SMITH, ESQ</p> <p>31 Attorneys for Defendant, Johnson & Johnson</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p>	<p>1 I N D E X</p> <p>2 WITNESS PAGE</p> <p>3 SUSAN NICHOLSON, MD</p> <p>4 Continued direct by Mr Placitella 207</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11 ALL EXHIBITS/DOCUMENTS ARE LISTED ON PAGES 356-357</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 A P P E A R A N C E S (Cont'd):</p> <p>2</p> <p>3 O'TOOLE, FERNANDEZ, WEINER & VAN LIEU</p> <p>4 14 Village Park Road</p> <p>5 Cedar Grove, New Jersey 07009</p> <p>6 973-239-5700</p> <p>7 BY: GARY VAN LIEU, ESQ.</p> <p>8 Attorneys for Defendant, Colgate-Palmolive</p> <p>9</p> <p>10 McCARTER & ENGLISH, LLP</p> <p>11 Four Gateway Center</p> <p>12 100 Mulberry Street</p> <p>13 Newark, New Jersey 07102</p> <p>14 973-622-4444</p> <p>15 BY: JOHN C. GARDE, ESQ.</p> <p>16 Attorneys for Defendant, Johnson & Johnson</p> <p>17</p> <p>18 ALSO PRESENT:</p> <p>19 Carolyn McNelis, Paralegal, Cohen Placitella & Roth, PC</p> <p>20 Vincent Maggiano, Videographer, Dynamic Evidence</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 THE VIDEOGRAPHER: The time is 10:08 a.m.</p> <p>2 We are now on the video record. Today's date is</p> <p>3 March 6, 2019. This is the videotaped deposition of</p> <p>4 Susan Nicholson. Counsel will be noted in the</p> <p>5 stenographic record. May the court reporter swear</p> <p>6 in the witness and then you may proceed.</p> <p>7</p> <p>8 S U S A N N I C H O L S O N, MD, sworn:</p> <p>9</p> <p>10 CONTINUED DIRECT EXAMINATION BY MR. PLACITELLA:</p> <p>11</p> <p>12 Q Good morning, Dr. Nicholson, how are you?</p> <p>13 A Good morning. Thank you.</p> <p>14 Q As you know that after your last</p> <p>15 deposition we had a conference with the court?</p> <p>16 A Yes.</p> <p>17 Q And it was pointed out to me by the court</p> <p>18 that at certain points in the deposition I could</p> <p>19 have been a little bit more polite to you, and if I</p> <p>20 was impolite in any way, I apologize.</p> <p>21 A Apology accepted.</p> <p>22 Q The court also indicated that there were</p> <p>23 times when maybe you could have been a little bit</p> <p>24 more responsive to my questions. So I told the</p> <p>25 court we would try to work together to try to get</p>

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<p>1 this done. Can we agree?</p> <p>2 A Yes.</p> <p>3 Q We are here in the courthouse now having</p> <p>4 the deposition taken in the courtroom of the</p> <p>5 Honorable Ana Viscomi, and the court will be</p> <p>6 available should we have any issues that we need to</p> <p>7 deal with. Do you understand that?</p> <p>8 A Yes.</p> <p>9 Q Now, since the last time we were together,</p> <p>10 did you review any additional materials?</p> <p>11 A No.</p> <p>12 Q Did you speak to any fact witnesses?</p> <p>13 A No.</p> <p>14 Q Did you discuss the substance of your</p> <p>15 prior testimony with counsel?</p> <p>16 A No.</p> <p>17 Q Has anything happened since the last time</p> <p>18 we were together and today that would cause you to</p> <p>19 change any part of your testimony?</p> <p>20 A No.</p> <p>21 Q Did you spend any additional time between</p> <p>22 the last deposition and today in preparing for your</p> <p>23 deposition?</p> <p>24 A I just looked over the same documents</p> <p>25 again briefly.</p>	<p>1 had occurred.</p> <p>2 Q Were any of these notes based upon any</p> <p>3 conversations with anyone?</p> <p>4 A The attorneys and I did review these notes</p> <p>5 together, but these notes are my notes to guide my</p> <p>6 recollection of the events that occurred.</p> <p>7 Q The notes were based solely on a review of</p> <p>8 documents that were supplied to you. Is that fair?</p> <p>9 A No. There was mention of the Reuters</p> <p>10 articles, which was an article I had read and</p> <p>11 conversations with individuals that we had mentioned</p> <p>12 previously, some notes related to that.</p> <p>13 Q I'm assuming that Prosecco had nothing to</p> <p>14 do with this particular deposition, other than you</p> <p>15 probably thought you needed a drink before you got</p> <p>16 in here?</p> <p>17 A No. I was asked to stop on the way home</p> <p>18 and made the note.</p> <p>19 Q Stop for Prosecco, and I've had witnesses</p> <p>20 tell me I'm challenging, but usually not that they have</p> <p>21 to drink before they come to the deposition.</p> <p>22 A Certainly not.</p> <p>23 Q Let's just walk through your notes so I</p> <p>24 have a sense of what is in here. I won't spend very</p> <p>25 long on it.</p>
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<p>1 Q In your preparing to begin the deposition,</p> <p>2 how much time did you spend, approximately, doing</p> <p>3 that?</p> <p>4 A Probably eight hours.</p> <p>5 Q So like one full day?</p> <p>6 A Well, spread across many days, but eight</p> <p>7 hours, I would say.</p> <p>8 Q You currently are an employee at Johnson</p> <p>9 and Johnson, right?</p> <p>10 A Yes, I am.</p> <p>11 Q And your title again is?</p> <p>12 A Vice-President Women's Health.</p> <p>13</p> <p>14 (PER COUNSEL AGREEMENT, THIS IS THE</p> <p>15 START OF CONFIDENTIAL PORTION BOUND UNDER</p> <p>16 SEPARATE TRANSCRIPT.)</p> <p>17</p> <p>18 Q Last time we marked as P-2 your notes. Do</p> <p>19 you have copies of your notes with you?</p> <p>20 A Yes.</p> <p>21 Q What were the circumstances under which</p> <p>22 you wrote these notes?</p> <p>23 A In reviewing the binders of documents that</p> <p>24 had been provided, I took some notes to create</p> <p>25 context over time for a number of the events that</p>	<p>1 The first thing you say is 1960s, and</p> <p>2 I'll put them under the Elmo so we are all on the</p> <p>3 same page. You say 1960s gras. Read it and tell me</p> <p>4 what you mean by that?</p> <p>5 A In the 1960s talc was reviewed in May,</p> <p>6 gras, generally regarded for safe and use in food</p> <p>7 products.</p> <p>8 Q You have here John Bailey, 1968 joined.</p> <p>9 What does that mean?</p> <p>10 A Tab A of, I don't know which binder, the</p> <p>11 large binder with all the tabs. I don't know what</p> <p>12 number it is. Tab A has an expert report from Dr.</p> <p>13 John Bailey from the FDA and PCPC.</p> <p>14 He joined the FDA in 1968 and then he</p> <p>15 wrote or provided this expert report from his</p> <p>16 experience starting with the FDA to temporary times.</p> <p>17 Q This expert report was is not a Johnson</p> <p>18 and Johnson document, correct?</p> <p>19 A No.</p> <p>20 Q Is it an expert report he actually</p> <p>21 prepared for another defendant in a talc case?</p> <p>22 A I don't know the source of this. I do</p> <p>23 know that John Bailey wrote it as an expert report</p> <p>24 related to the topic of talc safety.</p> <p>25 Q So how did you get it?</p>

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<p>1 A The attorneys gave it to me as part of the 2 file we have related to the take. 3 Q Is he an expert that you hired to assist 4 you in these litigations? 5 A I'm not aware that we have hired him and I 6 wouldn't necessarily know the answer to that 7 question. 8 Q The next thing you have here is 1970s. 9 Could you read what you wrote here and tell me why 10 you wrote it down? 11 A So 1971, the head of the EPA had a 12 symposium related to asbestos in talc and a number 13 of individuals were invited to that. That led to 14 Dr. Lewin's testing of a number of cosmetic talc 15 samples and that eventually led to the formation of 16 the J41 standard. 17 Q Then you have here 1980s. What is that? 18 A In 1984 the first citizen petition was 19 filed. That was denied in 1986. 20 Q Then you have some notes under that, see 21 figure 2.1 page 5, food additives binder. What does 22 that mean? 23 A That means in the binder, the smaller 24 binder, I can't see over there on the desk, but in 25 the smaller binder there's a 1986 response to the</p>	<p>1 asbestos, and I'm assuming that means ovarian 2 cancer? 3 A Yes. 4 Q Why did you write that down? 5 A I would have to look at the citizen 6 petition. I believe both of those topics were 7 raised in that citizen petition. 8 Q And then 1995, you have notes for 1995. 9 What is that? 10 A The CTFA Task Force wrote a letter to the 11 FDA related to that citizen petition. 12 Q Then off to the left you have FDA tested, 13 and then you have three things. What is that? 14 A So as we discussed previously, the FDA did 15 testing in 1976 of cosmetic talc and they did 16 another survey in 2009 and 2010. 17 In 1986, as we discussed in detail 18 last time, the FDA did an extensive analysis of 19 inhalation exposure of talc and other related 20 materials that was put into the response to that 21 1984 citizens petition. 22 Q I'll ask you about that later. And 23 underneath that you have 2009, and you have notes 24 under there. What does that mean? 25 A There was a new citizen petition in 2008</p>
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<p>1 citizen petition, and they are on page 5, figure 2 2.2. There's a table that I made notation to make 3 reference to. 4 Q Okay. 5 A I would have to look at that to tell you 6 exactly what is in that figure. 7 Q Then under 1990s, what is that? 8 A The NTP Rat Study. That was a study that 9 was the methods in that were -- I shouldn't say the 10 methods, the conduct of that study was flawed. The 11 machine broke in the midst of doing that study and 12 led to a high stress situation, what's called 13 overload in the animals, and some of those animals 14 did display some pathology. It was the subject of 15 several documents discussions where experts in the 16 field determined that that rat study did not have 17 any relevance to human health. 18 Q Was that something that Johnson and 19 Johnson discussed with the FDA? 20 A That study has been brought up numerous 21 times with the FDA and would have been part of that 22 1994 ISRTP FDA workshop was one that Johnson and 23 Johnson participated in and members of the FDA were 24 present. 25 Q Then you have 1994 citizen petition,</p>	<p>1 that was part of an April 2014 response by the FDA. 2 I was looking at that because the topic for the 3 deposition today was communications between Johnson 4 and Johnson and the FDA. So I made a note that 5 Kathy Wiley, who was the J & J employee, had spoken 6 to the FDA in that time period, or communicated 7 with, I should say. 8 Q You have Stanley Milstein emailed John B. 9 What does that mean? 10 A I would have to go back and look at the 11 documents related to that period of time. Stanley 12 Milstein wrote an email, probably to John Bailey, 13 but I would have to verify that in the documents 14 that were provided. 15 Q Then underneath that you say PCPC handling 16 interaction. Can you read those notes and tell me 17 what they mean? 18 A So the topic for the deposition is 19 communications between FDA and Johnson and Johnson 20 and Johnson and Johnson and FDA. Around that event 21 of the 2009, 2010 testing, communications with the 22 FDA was through our trade association PCPC. So 23 direct communication between Johnson and Johnson and 24 FDA was at a very minimum and that's why I made note 25 of Kathy Wiley above that.</p>

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<p>1 Q And who is Kathy Wiley?</p> <p>2 A I don't know her exact role. She's long</p> <p>3 since left the company.</p> <p>4 Q When you say the company, do you mean</p> <p>5 Johnson and Johnson?</p> <p>6 A Yes.</p> <p>7 Q Then on the next page, I guess the flip</p> <p>8 side, you have some notes about December 2009. What</p> <p>9 is that?</p> <p>10 A Again, the question was if Johnson and</p> <p>11 Johnson communicated with the FDA, and I found a</p> <p>12 document that showed that John Lemmo, a Johnson and</p> <p>13 Johnson employee, attended a meeting with FDA in</p> <p>14 December 2009.</p> <p>15 Q What is that underneath?</p> <p>16 A 2014, the FDA denied citizen petition.</p> <p>17 Q Then you have a single line and you have</p> <p>18 Reuter's article lays out the theme. What did you</p> <p>19 mean by theme, by the way?</p> <p>20 A So as we discussed previously, there was a</p> <p>21 recent article published by Reuters in late 2018</p> <p>22 that took some of the facts that had been discussed</p> <p>23 related to talc safety and put them out of context,</p> <p>24 which made them difficult to understand the</p> <p>25 implications of. So this section of my notes really</p>	<p>1 information.</p> <p>2 Q You say, for example, we are not playing</p> <p>3 games with language, and then you say go to McCrone</p> <p>4 letters. Is that something you somehow relied upon</p> <p>5 to prove your point?</p> <p>6 A It is not proving a point and provided in</p> <p>7 the binders are two letters. One in the '70s and</p> <p>8 one in the late '80s written by McCrone, who did the</p> <p>9 testing for our production material of talc and</p> <p>10 other sort of evaluations of talc for asbestos.</p> <p>11 And, for instance, I believe it was 1986, McCrone</p> <p>12 said in the previous fifteen years they never seen</p> <p>13 asbestos in production material of talc.</p> <p>14 So whatever discussions had taken</p> <p>15 place in that 15 years prior, the McCrone testing</p> <p>16 letter basically says there's no asbestos in Johnson</p> <p>17 and Johnson talc.</p> <p>18 Q And that testing letter you are talking</p> <p>19 about, that doesn't have any testing results itself</p> <p>20 in it, does it?</p> <p>21 A No. It is talking about the body of</p> <p>22 testing that had been done for the previous 15</p> <p>23 years.</p> <p>24 Q We will do some of that later.</p> <p>25 Here you have under the similar thing,</p>
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<p>1 takes some of those facts that could be taken out of</p> <p>2 context and puts them in the historical context of</p> <p>3 what was happening at that time.</p> <p>4 Q What did you mean when you say lays out</p> <p>5 the theme?</p> <p>6 A For instance, this first note says we are</p> <p>7 not playing games with language. There was a lot of</p> <p>8 confusion about asbestos and the misclassification</p> <p>9 of asbestos historically. And when people use the</p> <p>10 term tremolite, they are -- It is sometimes put in a</p> <p>11 way where it implies that tremolite is asbestos and</p> <p>12 that is not true. So the precision of language and</p> <p>13 implication is critical to understanding the facts</p> <p>14 and events related to talc safety.</p> <p>15 Q So it says Reuters article, later pivot</p> <p>16 back to. Why did you write pivot?</p> <p>17 A Meaning, if an individual fact, for</p> <p>18 instance, from some period between 1971 and 1976, if</p> <p>19 an individual communication is taken out, that</p> <p>20 almost certainly is misleading because at that time</p> <p>21 scientists, the FDA, really no one had any agreement</p> <p>22 on what the appropriate testing was for asbestos.</p> <p>23 So taking that out of -- pivot back</p> <p>24 to means provide the context for those individual</p> <p>25 points to be sure that there's no misleading</p>	<p>1 no documentation that a validated positive test for</p> <p>2 asbestos, then that material was used. Can you</p> <p>3 tell me what all that is?</p> <p>4 A In essence, we have standards, release</p> <p>5 specifications, certificates of analysis, for</p> <p>6 instance, that are related to how we manufacture and</p> <p>7 test our products. And any lot that is released to</p> <p>8 make production material needs to pass those</p> <p>9 standards, and one of those standards is no asbestos</p> <p>10 detected.</p> <p>11 Q And that is something you have personal</p> <p>12 knowledge of or information you gleaned from looking</p> <p>13 at documents?</p> <p>14 A I'm sorry, I don't really understand the</p> <p>15 question. There's two things there.</p> <p>16 Q Was it part of your job to do this or is</p> <p>17 this something you learned in preparation for being</p> <p>18 a witness?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A I don't mean to be evasive. I'm trying to</p> <p>21 understand the question. In my prior role as</p> <p>22 Vice-President Safety Surveillance and Risk</p> <p>23 Management for the Consumer Products, it was my job</p> <p>24 to oversee the safety of all products that we make</p> <p>25 in Consumers.</p>

<p style="text-align: right;">Page 220</p> <p>1 So my team, and myself, that was our 2 primary job, and one of those jobs is to ensure that 3 the specifications relevant to medical implications 4 of the use of our products are appropriate. 5 So, yes, understanding those 6 standards was part of my job. I have looked at 7 those standards, read them, discussed them with our 8 quality engineers, reviewed many, many test results 9 from over the years, so I have first hand knowledge 10 those standards are appropriate and implemented 11 100 percent of the time. 12 Q We will get to that. Then you say 13 underneath that, and I assume that means the 14 standards were set such that exposures less than 15 environmental exposures, then you have a bunch of 16 language. Could you explain that? 17 A Yes. So the standards were set between 18 that period of 1971 and 1976, and that was a 19 discussion with many experts in the field and again, 20 it is well described in that 1986 response to the 21 citizen petition. 22 The standards were set such that any 23 exposure someone might theoretically get with the 24 testing limitations that are set by the J41 standard 25 would be -- I think I have to go back, but certainly</p>	<p style="text-align: right;">Page 222</p> <p>1 Another scientific group got together 2 with the FDA and Dr. Lewin and determined that Dr. 3 Lewin's testing methods were inadequate and he was 4 misreading largely chlorite for chrysotile asbestos, 5 and he later retracted his results publically. And 6 Pooley and McCrone were two of the expert groups who 7 looked at those samples and determined that there 8 were not, in fact, asbestos in them. 9 The FDA retested those samples, found 10 there was not, in fact, asbestos in them, and then I 11 make a note here that there are miners and millers 12 that handled the very talc used that was used in 13 these products, and despite many years of 14 occupational exposure to those materials, there was 15 no evidence there was asbestos-related disease in 16 those miners or millers of cosmetic grade talc. 17 Q Let's go through your notes and we will 18 back and touch on all of these. 19 Next, Boundy study '75, '76. Tell me 20 what's in your notes. 21 A I would have to go back and pull the 22 Boundy study. 23 Q Rachel, no read, Rubin and discuss. What 24 does that mean? 25 A Rubino. This is Rachel Weinstein, who is</p>
<p style="text-align: right;">Page 221</p> <p>1 less than a lifetime exposure of asbestos just 2 breathing air. 3 So the calculation and the testing 4 methods were set such that there was no chance that 5 the exposure you would get from using talc would 6 come anywhere close to what you would get in normal 7 day-to-day life. 8 Q We will spend some time. I just want to 9 understand your notes. 10 On the next page 3, you say ACP, 11 Langer, Pooley, Lewin. Tell me what all that is. 12 A I don't remember what ACP means, but I do 13 know Dr. Langer from Mount Sinai did testing of talc 14 in the early '70s. He thought he had seen asbestos. 15 Many experts looked at those results 16 and determined that, in fact, he was incorrect, that 17 what he had seen what's called rolled talc and he 18 later retracted saying those were not his results 19 and they were preliminary and in effect, he had made 20 a mistake. 21 Q Okay. 22 A Dr. Lewin, similarly he was hired in the 23 early '70s by the FDA to test cosmetic talc and he 24 tested more than 100 samples and thought that he had 25 seen many samples that contained asbestos.</p>	<p style="text-align: right;">Page 223</p> <p>1 a PhD epidemiologist at Johnson and Johnson. And 2 Rubino is one of the Miner, Miller studies, and I 3 was interested in understanding if there was any 4 critique of the methods that were used, anything 5 perhaps that I should understand more than I did by 6 reading it myself. 7 We did discuss it and my 8 understanding of the results were what I thought 9 they were. The other one was just a random note. 10 Q Email travel dates. What is July 15th, 11 case starts? What does that mean? 12 A I was told there could be a case that they 13 would like me to help prepare for. 14 Q I'm getting there. Talk to me about the 15 notes on the next page that I have here starting 16 with Natasha. Go through your notes for me. 17 A So Natasha is our head of, and I have to 18 look up her last name, is the head of quality for 19 Consumers. She started after I left my Consumer 20 role. She has knowledge of the history of testing 21 of asbestos and I wanted to confirm some of my 22 recollection of our worldwide testing program, and 23 those notes below that are related to the questions 24 that I wanted to get clarification that we have been 25 doing a worldwide testing for asbestos since the</p>

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<p>1 year 2000 to present where we pull material off the 2 shelves and test for asbestos.</p> <p>3 Pre 2000 we did -- the redundancy was 4 that not only do J41, but we use electron microscopy 5 sampling and so forth.</p> <p>6 Q Here you have 1938 FDCA. What does that 7 mean?</p> <p>8 A Food and Drug Cosmetic Act was adopted in 9 1938.</p> <p>10 Q And then you have underneath that a 11 Jifsan.UMD.edu. What is that all about?</p> <p>12 A In the fall of this past year the FDA had 13 a meeting that industry did not participate in to 14 discuss current methodologies for asbestos testing 15 in talc.</p> <p>16 Some of the individuals who attended 17 that meeting had acted as experts for Johnson and 18 Johnson, which we disclosed to the FDA. Related to 19 the topic of the deposition, which is communications 20 Johnson and Johnson has with the FDA and FDA has 21 with Johnson and Johnson, we did communicate to them 22 some of those individuals had functioned as experts 23 on this matter for Johnson and Johnson.</p> <p>24 Q And who were those individuals?</p> <p>25 A I would have to check other notes to</p>	<p>1 meeting. I don't know that we supported their 2 travel to that meeting or not. I would have to 3 verify whether or not that's true.</p> <p>4 Q When you took these notes down, where were 5 you and who were you talking to?</p> <p>6 A I don't recall.</p> <p>7 Q But your notes say, as it relates to the 8 November meeting, "paid for the people to go to 9 meeting." Correct? That's what they say?</p> <p>10 A I didn't put them in quotations. That was 11 a note to myself to verify whether or not that was 12 true. I guess I forgot to put a question mark 13 there.</p> <p>14 I don't know whether we did or did 15 not pay for individuals to go to the meeting. But 16 those experts that participated in the meeting were, 17 in fact, people that had worked for Johnson and 18 Johnson as experts on the talc related safety 19 issues.</p> <p>20 Q Did they work for Johnson and Johnson as 21 experts in litigation?</p> <p>22 A They worked for experts. I don't recall 23 the exact names of the experts, so I don't know what 24 capacity they might have worked on. I have not 25 worked directly with any of these experts to my</p>
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<p>1 verify. I don't know right off the top of my head.</p> <p>2 Q Then here it says paid for people to go to 3 meeting. What does that mean?</p> <p>4 A I would have to check. I understood we 5 had hired those experts previously and they had 6 worked for Johnson and Johnson. I'm not -- I have 7 not confirmed, in fact, anybody supported the travel 8 of those individuals to the meeting. I would have 9 to double check that.</p> <p>10 Q Why did you write down paid for people to 11 go to meeting?</p> <p>12 A These are my notes. I would call it an 13 aid memoir. Things to stimulate my memory so that I 14 would, as I was looking through documents, be on the 15 lookout for those things. So they are not declared 16 as statements per se, but comments to help stimulate 17 my memory as I look through what amounts to many 18 hundreds and hundreds of pages of documents.</p> <p>19 Q I get that, but you talk about a meeting 20 in November. You say that it was not for industry, 21 but then your notes say that you paid for people to 22 go to the meeting. Why did you write that down?</p> <p>23 A So I did not say that we paid for people 24 to go to the meeting. We have employed as experts 25 some of the individuals that participated in that</p>	<p>1 recollection.</p> <p>2 Q You wrote Mike Fedala worked together. 3 What is all that?</p> <p>4 MR. SMITH: Objection.</p> <p>5 Q I highlighted it. What do notes mean?</p> <p>6 A So we were -- I was talking to a number of 7 individuals and Tim is Tim McCarthy, trying to 8 understand how we learned about the meeting that FDA 9 was calling on November 28th.</p> <p>10 So the topic for the deposition was 11 communications between Johnson and Johnson and the 12 FDA and FDA and Johnson and Johnson. We had met 13 with FDA in June and I was trying to recreate how it 14 is that Johnson and Johnson had gotten 15 communications from the FDA about that meeting.</p> <p>16 So I asked Tim, and apparently there 17 were a number of people sending emails, and that's 18 how this meeting came about. Someone named Mike 19 Fedala called Tim who used to work with Stanley 20 Milstein, who is now with the FDA, who sent an 21 email to Tim.</p> <p>22 Anyway, that's related to how we knew 23 that the FDA was interested in having a discussion.</p> <p>24 Q Underneath it you have a star and it says. 25 "How were the three experts selected?" What did</p>

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<p>1 you mean by that?</p> <p>2 A So in that meeting in June, the FDA asked</p> <p>3 us if we had recommendations of experts in asbestos</p> <p>4 testing. They specifically said they do not</p> <p>5 internally have that expertise, and if we had anyone</p> <p>6 that should be considered as possible participants,</p> <p>7 that we should submit those names. And apparently</p> <p>8 we gave three expert name recommendations, and I was</p> <p>9 trying to figure out how we selected those</p> <p>10 particular names.</p> <p>11 Q Was one of them Ann Wiley?</p> <p>12 A Not that I recall, but again, I don't</p> <p>13 remember the exact names of the experts.</p> <p>14 Q Then you say Lynne --</p> <p>15 A This is Lynne Szczepaniak.</p> <p>16 Q Then you have "no." What does that mean?</p> <p>17 A I was trying to get -- we mentioned before</p> <p>18 that one of the people I reached out to was Lynne</p> <p>19 Szczepaniak, who was our Global Head of Regulatory</p> <p>20 Affairs for Consumer to ask her if she knew where</p> <p>21 the three expert names came from and how we picked</p> <p>22 them.</p> <p>23 Q What did you find it?</p> <p>24 A She didn't know. I asked her if, also</p> <p>25 related to communications to and from the FDA, if</p>	<p>1 page 1. I spoke to Don Hicks and John Hopkins about</p> <p>2 these topics. Then there was a note about something</p> <p>3 else I was working on at the same time.</p> <p>4 Q Did you speak to Hicks or Hopkins in</p> <p>5 reference to this deposition?</p> <p>6 A Not in reference to this deposition.</p> <p>7 Q To prior testimony you gave?</p> <p>8 A Don related to -- Don and I worked</p> <p>9 together, so we have talked many times about</p> <p>10 asbestos testing and I made note that either one</p> <p>11 these two gentlemen would have additional</p> <p>12 information related to asbestos testing if needed,</p> <p>13 but I didn't feel after reviewing the documents I</p> <p>14 needed to discuss with them further.</p> <p>15 Q The last time we were together one of the</p> <p>16 things we reviewed were what representations Johnson</p> <p>17 and Johnson made to the FDA concerning the asbestos</p> <p>18 content of Johnson and Johnson's cosmetic talc. Do</p> <p>19 you recall that?</p> <p>20 A Yes.</p> <p>21 Q And I believe you are testified that the</p> <p>22 issue of whether there was any evidence of asbestos</p> <p>23 in Johnson and Johnson cosmetic talc was raised</p> <p>24 repeatedly over the years by the FDA, correct?</p> <p>25 MR. SMITH: Objection.</p>
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<p>1 any FDA had reached out after the Reuters article</p> <p>2 was published and she said no.</p> <p>3 Q Then the next thing you have is bold</p> <p>4 initiative. What does that mean?</p> <p>5 A Unrelated to this topic, but it has to do</p> <p>6 with looking at the talc safety issue and putting</p> <p>7 together a compendium of scientific information</p> <p>8 related to that. That was a topic that Lynne and I</p> <p>9 also discussed.</p> <p>10 Q And you have the word briefing book. What</p> <p>11 is the briefing book?</p> <p>12 A There's no briefing book. This was a</p> <p>13 discussion around putting a compendium of scientific</p> <p>14 information that would be similar to a briefing book</p> <p>15 they might prepare for FDA, for instance.</p> <p>16 Q And was that prepared?</p> <p>17 A No, we have not prepared that.</p> <p>18 Q The last page, page 5, can you just go</p> <p>19 through that in order and tell me what all this</p> <p>20 means. It starts with '60s, Bailey.</p> <p>21 A So this is redundant. In the '60s, Bailey</p> <p>22 had some summary in his expert report that I made</p> <p>23 reference to earlier.</p> <p>24 There are a number of documents about</p> <p>25 Langer and it points to tab B of this large binder,</p>	<p>1 A Could you please repeat the question?</p> <p>2 Q Sure. You testified last time that the</p> <p>3 issue of whether there was any evidence in asbestos</p> <p>4 in Johnson and Johnson talc was raised repeatedly by</p> <p>5 the FDA to Johnson and Johnson over the years,</p> <p>6 correct?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A Yes, but it was more around testing, not</p> <p>9 the presence of asbestos, to clarify your question.</p> <p>10 Q I'm going to go to your testimony last</p> <p>11 time at page 87, line 10. I'm going to play for you</p> <p>12 your testimony.</p> <p>13</p> <p>14 (Videotape played from previous</p> <p>15 testimony)</p> <p>16</p> <p>17 Q Now, am I correct whether there was</p> <p>18 asbestos in the Johnson and Johnson talc products</p> <p>19 was raised repeatedly by the FDA beginning in the</p> <p>20 early '70s?</p> <p>21 A It was raised. I don't know what that</p> <p>22 means.</p> <p>23 Q The issue was, the question came up over</p> <p>24 and over again, beginning in the 1970s, and was</p> <p>25 posed to Johnson and Johnson, whether any Johnson</p>

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<p>1 and Johnson talc product contained asbestos. Can we 2 agree with that? 3 MR. SMITH: Objection. 4 A That's correct and Johnson and Johnson 5 talc never contained asbestos. 6 BY MR. PLACITELLA: 7 Q Do you recall giving that testimony? 8 A I do, yes, and -- 9 Q That's my question 10 Do you recall giving 11 that testimony? 12 A Yes. 13 Q Do you recall telling me last time that 14 the answer always was that there was never any 15 evidence of any amount of asbestos in Johnson and 16 Johnson talc? 17 A I would have to understand the context of 18 that answer. 19 Q I'll play your testimony from the last 20 time again. 21 (Videotape played from previous 22 testimony) 23 Q The answer by Johnson and Johnson was 24 always the same, correct? 25 That is, there is no evidence of</p>	<p>1 A I hear what you are saying, yes. 2 Q Ultimately we will let the experts and the 3 court and the jury determine whether what you 4 disclosed or didn't disclose was significant or not. 5 Can we agree? 6 MR. SMITH: Objection. 7 A That's fine, yes. 8 Q I want to approach you for a second with 9 volume 1. I'm not being rude here, and as I recall 10 volume 1, which is marked P-3, it is a compendium of 11 everything you ever sent to the FDA, concerning 12 testing of Johnson and Johnson cosmetic talc for 13 asbestos. Correct? 14 A Not exactly, no. 15 Q What is volume one? 16 A Volume 1 is a representative of the 17 communications that we had back and forth with the 18 FDA. Substantive documents are here and multiple 19 copies of the same topic are not necessarily 20 included. 21 If you pull out tab C, which I've 22 done and put over here, there were a number of 23 documents from the early '70s that we could not 24 locate, and so they are not necessarily included in 25 that binder.</p>
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<p>1 any asbestos of any -- strike that. 2 The answer provided by Johnson and 3 Johnson was always the same. There is no evidence 4 of any amount of any asbestos in any of Johnson and 5 Johnson cosmetic product, correct? 6 A There was no asbestos in Johnson and 7 Johnson products, correct. 8 Q Do you recall giving that testimony? 9 A Yes. 10 Q Now, today I want to spend some time 11 reviewing exactly what information was provided by 12 Johnson and Johnson to the FDA to support those 13 representations. 14 We are on the same page? 15 A Yes. 16 Q And I also want to explore what 17 information was in the possession of Johnson and 18 Johnson that was not provided to the FDA. 19 Are you with me? 20 A I don't know what you are referring to, 21 but I hear what you are saying. 22 Q On the subject of asbestos testing in 23 Johnson and Johnson talc. 24 We are going to go through 25 that. Are you with me?</p>	<p>1 Q Everything you could find in terms of 2 communications with the FDA written is in volume 1, 3 P-3, correct? 4 A Not exactly. Anything of substance is 5 here that I'm aware of. 6 Q And you have a copy, a duplicate of this 7 in front of you? 8 A Yes, I do. 9 Q So what I want to do now is I want to make 10 sure we are all on the same sheet of music, okay, in 11 terms of what is in this book and what was provided 12 to the FDA. Okay? 13 A Yes. 14 Q Are you with me? So what I would like you 15 to do is go through the binder with me and let's 16 just make sure we have a clean record of everything 17 in this binder that was provided to the FDA on the 18 subject of whether any test -- scratch that. Let me 19 do it again. 20 Let's go through the binder and make 21 sure we are in agreement on the same sheet of music 22 as to what testing results were provided to the FDA 23 by Johnson and Johnson concerning asbestos in 24 Johnson and Johnson talc products. Are you with me? 25 A Yes.</p>

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<p>1 Q Why don't you start and I'll mark my book 2 at the same time. Let's walk through the book. 3 A I'm sorry, what information do you want? 4 Q I want to go through and mark in the book 5 on the record what testing results you transmitted 6 to the FDA. You, Johnson and Johnson, for asbestos 7 in cosmetic talc that was sold by Johnson and 8 Johnson. Okay? 9 A Okay. In tab 1 there's a memo here making 10 note of three different reports on talcum powder 11 that was transmitted to the FDA. 12 Q The memo you are talking about is July 8, 13 1971? 14 A Correct. 15 Q That's a correspondence from Johnson and 16 Johnson to the FDA, correct? 17 A Correct. 18 Q But those aren't the results themselves. 19 The results are attached, correct? 20 A Correct. 21 Q So what are the results? Let's just talk 22 about the results so we make sure. 23 A Well, the particle size distribution does 24 not have to do with asbestos, so we can go past 25 there one. Number 2 is x-ray analysis of 344L,</p>	<p>1 A Thank you. This is x-ray analysis, which 2 has a limit of detection. 3 Q I'm going to go through each one with you 4 I promise and you can talk about it. All I want to 5 do is identify and then we will go back through each 6 one. Okay? 7 A Okay. 8 Q I want to make sure we are on the same 9 sheet of music. Okay? 10 A Okay. I'm following. 11 Q The next test I can find was under 9, tab 12 9A. Let me know if you see one in between. There's 13 a reference in July 9, 1971 to the FDA meeting 14 July 8th. Dr. had shared electron microscopy 15 photographs at a meeting. 16 Q But there are no test results in that, is 17 there? Raw results from an expert? 18 A Well, I believe that electron micrograph 19 would be a test result. If you can clarify the 20 definition, then maybe we can. 21 Q I'm looking for the reports that you gave 22 to the FDA concerning the test results related to 23 asbestos in talc. 24 A So you want only reports? 25 Q Yes, the solid reports.</p>
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<p>1 which is a representative sample from Vermont. 2 Q Okay. Where is that? 3 A I'm looking. 4 Q Is that the Dartmouth report? 5 A The third one is the Dartmouth report. 6 Q That's June 28, 1971? 7 A That's correct. 8 Q Okay. 9 A And that's attached. None of the results 10 here mention, that I can see just on a glance, the 11 presence or absence of asbestos, but it talks about 12 a number of other substances that were looked at, 13 for instance, chlorite and such. 14 Q Well, actually, if you go to page 5 of the 15 report, and we will back to it, it does talk about 16 results on number 10, doesn't it? 17 A You are correct. No amphiboles or 18 asbestos were observed. Thank you. 19 Q Then am I correct the next set of tests is 20 a July 7, 1971, from the Colorado School of Mines? 21 A That is correct. I'm looking for that 22 report. 23 Q I think it is the very next page. 24 A Thank you. 25 Q I'll pull it up here on the screen.</p>	<p>1 A Okay. There are meetings minutes that 2 refer to a number of tests. I'm looking at 9, as 3 you point out, and there's a reference to a series 4 of reports. There's the Pooley report, the McCrone 5 report, a letter from the Colorado School of Mines, 6 a report on particle size, another report from Dr. 7 Pooley and some reports from the McCrone folks. 8 Q Okay. Let's identify them. Under 9A you 9 have the Pooley report? 10 A Yes. 11 Q I'll put a tab there. The next report I 12 see is 9D from McCrone. Is that correct? 13 A There are other reports related 14 specifically to asbestos testing, I believe is your 15 question. 16 Q Correct. 17 A There is a report in tab C that makes 18 reference to numerous different types of evaluations 19 of talc product. 20 Q Are there any results of the asbestos 21 testing in 9C, because I didn't see them? Actually, 22 you are correct. I think this is repeated. Okay. 23 So 9C. 24 A In conclusion, it makes reference to 25 testing for asbestos.</p>

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<p>1 Q I got it. Where it says samples 1 through 2 10, right? 3 A Correct. 4 Q We will come back to that? 5 A The next report is from McCrone on 344L 6 sample. 7 Q That's dated August 19, 1971? 8 A Yes. 9 Q I have it up on the screen. To make sure 10 we are all on the same page. 11 A Yes. 12 Q What is the next one? 13 A This is not results, but in tab E is the 14 methods used by McCrone. 15 Q They don't contain any results? 16 A Correct. 1971 to 1976, the methods were a 17 primary focus on testing. 18 Q I promise I'll give you all the time you 19 need to talk about those things. 20 The next one I have is tab 27. Mine 21 says 27A, Sperry-Rand. 22 A Tab 14 makes mention of internal J & J 23 testing of the same samples or samples from the same 24 lots that Professor Lewin had tested. There's a 25 report, but there's a communication to the FDA, our</p>	<p>1 Q But those actual tests results are here, 2 right, in this book, the McCrone results? 3 A I would have to track to make sure it is 4 the exact sample they are making reference to. 5 Q There's no test results on page 2, it is 6 just a summary statement, correct? 7 A That's the test results were reported to 8 the FDA. That's what it says. I thought that's 9 what you were asking. 10 Q I want to just highlight it. So you are 11 talking about now tab 16? 12 A Tab 16. 13 Q On page 2? 14 A Yes. Second paragraph. Dr. Stewart, from 15 McCrone Associates, reviewed his findings on the 16 Lewin Shower to Shower sample. He stated all 17 samples were subject to electron microscopy. No 18 chrysotile present at the end of that paragraph. 19 MR. SMITH: I want to place my 20 objection to highlighting on the originals. I 21 object to it. I don't think you should do it. 22 MR. PLACITELLA: I'm doing it so we'll 23 have it. She has got a copy. 24 MR. SMITH: My copy. 25 MR. PLACITELLA: Okay.</p>
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<p>1 test showed no asbestos in samples. 2 Q I want to make sure I got that. That's 3 tab 25C? 4 A This is tab 14 I'm looking at, August 8, 5 1972. 6 Q My fault. Sorry. August 8, 1972? 7 A Correct. 8 Q Make sure we have a picture of that. 9 That's it, right? 10 A Yes. 11 Q Go ahead. Keep going. 12 A There's another mention in the document in 13 15, which is a memorandum of a meeting by the FDA 14 That's on page 3. It is referencing to the same 15 testing results. 16 Q But the results are on tab 14, correct? 17 A The same information is conveyed in both 18 of those documents. 19 Q What is next? 20 A There's reference in tab 16 that McCrone, 21 in addition to the J & J scientists' role, and one 22 other scientist mentioned in those two previous 23 documents on page 2, there's mention of McCrone also 24 testing the Lewin Shower to Shower sample and 25 finding that there was not asbestos in that sample.</p>	<p>1 Q What is the next document? 2 A There's some back and forth in August 3 about additional looks at various samples. 4 Q But no results, no published results, 5 correct? No reports? 6 A No, but communication to the FDA regarding 7 reports. 8 Q I'm going to go through that. All I'm 9 trying to do now is identify the actual reports that 10 were provided. Are we on the same page? 11 A I understand. 12 Q Okay. So what is the next actual physical 13 report that's in this binder you provided? 14 A There's a September memo that makes 15 reference to data shared by Dr. Pooley with the FDA. 16 The actual report is not here, but reference to a 17 communication of test results is made note of. 18 Q What is the actual report, the next actual 19 report that you provided? 20 A I realize you are asking for a physical 21 report. There are multiple communications that 22 reference data that isn't in a specific report, but, 23 forgive me, I'm going page by page to make sure to 24 get what you need. 25 Q Go ahead.</p>

<p style="text-align: right;">Page 244</p> <p>1 A There's a memo in tab 26, I believe you 2 referenced before, looking at some analyses that 3 were done from McCrone. And there's some scanning 4 electron micrographs included, and I think that 5 might fall under your definition of report. 6 Q Tell me what you are referring to. 7 A Tab 26, memo to Ian Stewart from Walter 8 McCrone. 9 Q I don't see anything on tab 26 itself. 10 I'm sorry. 26. Show me where in tab 26 are you 11 referring to. I have it up on the screen. 12 A Starting on page 3, there are electron 13 micrographs. I think that might meet your 14 definition of a report. 15 Q Okay. And that's identified? 16 A Tab 27, there are multiple reports here on 17 the Italian mine investigation of Shower to Shower 18 included in the tabs following tab 27. 19 Q Let's identify each one, please. 20 A October 17, 1972 to Dr. Schaefer. 21 Q That's the cover letter, correct? 22 A Correct. The reports are listed there. 23 Q So A, tab A is a report from Sperry-Rand? 24 correct, dated September 8, 1972? 25 A Yes.</p>	<p style="text-align: right;">Page 246</p> <p>1 that was delivered to Dr. Schaffner on February 14, 2 1973. I'm looking at Talc Versus Asbestos in Long 3 Term Animal Studies. The report itself it appears 4 was not retrieved. 5 Q Okay. 6 A The next one is -- I don't see the date on 7 the report. The cover letter is dated May 25, 1973. 8 Q Okay. The next report I was able to 9 identify is in tab 36, but you can verify that for 10 me? 11 A That's what I find as well, November 9, 12 1973. 13 Q So there's a cover letter from Johnson and 14 Johnson to Dr. Schaefer and it attaches various 15 reports related to Shower to Shower, correct? 16 A That is correct. 17 Q And the first report is from Martin 18 Buerger, October 7, 1972? 19 A That is correct. 20 Q The next report is from Gordon Brown? 21 A That is correct. 22 Q The next report after that is from McCrone 23 dated June 22, 1973? 24 A That is correct. 25 Q The next report is from Colorado School of</p>
<p style="text-align: right;">Page 245</p> <p>1 Q Tab B is correspondence, right? Tab C, I 2 have an October 27, 1972 report from Colorado School 3 of Mines. Is that right? 4 A Yes. 5 Q The next report I see is a report from 6 McCrone dated 10-27-72 concerning Johnson's Baby 7 Powder? 8 A That is correct. 9 Q The next report I see is a report from 10 Gordon Brown concerning an x-ray study of Johnson's 11 Baby Powder, correct? 12 A Yes. 13 Q The next report that I see is an October 14 31, 1972 report from Professor Pooley on baby 15 powder. Is that correct? 16 A Yes. The cover letter is dated in 17 November, but the report itself is October 31. 18 Q The next report I see is a November 8, 19 1972 report internally from Johnson and Johnson. Is 20 that fair? 21 A That's what it look looks like, yes. 22 Q And I don't see any other reports until 23 tab 31. Can you verify that? 24 A There's reference a report that I don't 25 see here in tab 30. It makes reference to a report</p>	<p style="text-align: right;">Page 247</p> <p>1 Mines, September 7, 1972, correct? 2 A That is correct. 3 Q The next report is from Dr. Pooley dated 4 September 29, 1972, correct? 5 A That is correct. The next is from Dr. 6 Pollack from Carnegie Mellon. 7 Q I don't see any results in this. It is 8 just a comment on Lewin's report, right? There's no 9 actual testing results in this one? 10 A Hold on. That's one interpretation. This 11 person has looked at those results and given their 12 interpretation. Although it is in a cover letter, 13 it is a report of an interpretation. 14 Q Okay. The next one is an internal report 15 from Johnson and Johnson, September 28, 1972? 16 A That is correct. 17 Q Are there any other reports, test results 18 like this after September 28, 1972? 19 A I'll have to continue to look to verify. 20 There's a report in tab 41. 21 Q Excuse me? 22 A Tab 41. 23 Q Okay. 24 A There's a report on detection at low 25 levels of chrysotile asbestos by differential</p>

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<p>1 thermal analysis. So it is a testing methodology 2 that related to our talc product. 3 Q But no test results. 4 A Do you mean -- what do you mean? 5 Q They looked at the Johnson and Johnson 6 talc, they ran a test and this is what they found. 7 With an actual test result. We found asbestos. We 8 didn't find asbestos. We found tremolite. We 9 didn't find tremolite. That's what I'm talking 10 about. 11 A One minute. I'm looking. This is a 12 methods paper on what the detection limits are. You 13 are right. It doesn't list this talc, this talc and 14 the other talc in the results of the test. 15 Q It didn't test the specific product and 16 say these are the results, it is just talking about 17 methods, correct? 18 A It is a methods paper. That's correct. 19 Q Would this be a good time to take a break 20 and kind of peruse it off the camera to see if 21 there's anything else? 22 A Sure. 23 THE VIDEOGRAPHER: The time is 11:20. 24 We are going off the video record. 25 (Recess taken)</p>	<p>1 asbestos and listed here. 2 Q Hold on. I have tab 50 as a May 16, 3 1975 -- 4 A I'm sorry. 52. 5 Q 52. 6 A This is a letter from George Sandlin, who 7 is chairman of FDA Talc subcommittee, Robert Schaffner 8 at the FDA. On page 2 it makes reference to a 9 number of cosmetic products that were tested for the 10 presence of asbestos. J & J products are included 11 in that. 12 Q The reference to a report by Dr. Pooley, 13 isn't that the earlier report we went over? 14 A I would -- it says all done by Pooley. I 15 would have to go back and double check they were the 16 same exact ones. 17 Q But there's no Pooley report. 18 A Correct. There's no report here, but 19 there's reporting of results to the FDA. 20 Q There's no analysis? 21 A I don't know what that means, analysis. 22 Q It doesn't have -- there's no report from 23 Dr. Pooley. It is somebody relating what they think 24 or believe Dr. Pooley found. There's no report from 25 Dr. Pooley, correct?</p>
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<p>1 2 THE VIDEOGRAPHER: The time is 11:34. 3 We are now back on the video record. Counsel, you 4 may proceed. 5 Q When we left off you were going through 6 the binder to identify any other testing report 7 related to whether or not there was asbestos in 8 Johnson and Johnson talc. Did you find any others? 9 A I did. 10 Q What is the next one you found? 11 A Tab 45. There's a letter to Arnold 12 Schelz at the FDA dated October 4, 1974. 13 In paragraph 2 it makes reference to 14 a report enclosed, which verifies the presence of 15 non fibrous varieties in talc. No chrysotile. The 16 report is not attached, but it makes reference to a 17 report. 18 Q But there's no report? 19 A Right, but you asked me about reports sent 20 to the FDA. 21 Q I just want to make sure we are on the 22 same page. 23 A Yes. Then tab 50. There's a note to Dr. 24 Schaffner at the FDA September 12, 1975, and on page 2 25 of the report of samples that were tested for</p>	<p>1 A These are results being reported from the 2 companies to FDA. So you are right, there isn't a 3 separate report from Dr. Pooley, but the results are 4 reported here. 5 Q We don't know what that refers to, whether 6 it is an earlier report, a new report. We have no 7 idea -- 8 A To your point a second ago, we could go 9 back and look at the Pooley report. I don't know 10 that this is the exact same results. 11 Q We will do that. Keep going. 12 A Tab 52 I believe refers also to those 13 same results, talking about Dr. Pooley and extensive 14 study of samples that offer some clarification of 15 the Pooley results. 16 Q But again, no official report from Dr. 17 Pooley? You do say on the second paragraph, Dr. 18 Pooley's summary report is attached as attachment B. 19 Where is attachment B? 20 A There's attachment A that looks like it is 21 the result in Tab K and there's an attachment B in 22 Tab L. 23 Q So attachment B. But attachment B isn't 24 of any Johnson and Johnson product, correct? It is 25 products from Australia, Brazil, South Korea, China.</p>

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<p>1 There's no specific test in attachment B related to 2 Johnson and Johnson products.</p> <p>3 A In 1975, material was being sourced from 4 Italy and talc origin in Italy, that would refer to 5 the source material for Johnson and Johnson talc.</p> <p>6 Q Where does it say that?</p> <p>7 A I know that to be true.</p> <p>8 Q You were still buying talc from Italy in 9 1975? There's no test results here saying this is a 10 Johnson and Johnson product and this is what we 11 found, correct?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A Correct. You asked about results reported 14 to the FDA. Results reported to the FDA. These are 15 the supporting documents and actual physical, 16 separate report is not included here. It may have 17 existed at some time and we don't have it. I'm 18 doing my very best to give you the information you 19 asked for.</p> <p>20 Q Okay. Keep going.</p> <p>21 A Tab 56 makes reference to testing done by 22 a number of companies. If we cross reference -- 23 I'll have to verify it that -- it may be the same 24 data presented on page 2. It delineates all the 25 reports of talc testing that had been done on</p>	<p>1 page. In tab 56 when it talks about tests of 2 Johnson and Johnson product, there is no report, 3 actual report from a scientist either that worked 4 inside of Johnson and Johnson or outside of Johnson 5 and Johnson for Johnson and Johnson. There's no 6 actual authored reports, correct?</p> <p>7 A That's correct. And for clarity, when we 8 share results of tests with the FDA, sometimes a 9 report is sent, sometimes the results are summarized 10 and communicated to the FDA and if they request the 11 report, we will offer to send the report.</p> <p>12 Sometimes it is sent and sometimes 13 it doesn't sent. That's why reporting of the 14 results would be the results whether there's not an 15 attached report.</p> <p>16 Q Keep going.</p> <p>17 A That's all I could find.</p> <p>18 Q Am I correct then that the last report of 19 any results of testing related to asbestos, 20 concerning Johnson and Johnson talc products, was 21 1976 in your book?</p> <p>22 A So, no, because there are test results 23 from the 2009 and 2010 survey that was done by FDA, 24 but that was not -- those aren't test results from 25 Johnson and Johnson or a contractor to the FDA.</p>
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<p>1 Johnson and Johnson talc.</p> <p>2 Q I think we are not on the same page, which 3 is why I'm going through this. 56 is a May 24, 1976 4 letter from Windsor Minerals to McCrone complaining 5 about asking lawyers for quick answers.</p> <p>6 A I'm looking at tab 56 in my book and it is 7 a March 19, 1976 letter.</p> <p>8 Q Okay.</p> <p>9 A On page 2 there's the cover letter and 10 then a subject memo, asbestos in talc, and then a 11 number of different companies are listed, including 12 Johnson and Johnson, which summarizes reports from 13 the numerous evaluations that have been done.</p> <p>14 Q But no actual report itself from a 15 scientist?</p> <p>16 A There's not a physical, separate report, 17 but it reports results from numerous different 18 studies that have been done.</p> <p>19 Q But there's no report directly authored by 20 a scientist, correct?</p> <p>21 A In this tab the source documentation that 22 you are referring to is not included, but there's a 23 listing of results that have been shared with the 24 FDA.</p> <p>25 Q I want to make sure we are on the same</p>	<p>1 Remember 1976, the J41 standard was 2 put in place, so all of the lots of talc would have 3 been tested by that standard and we would have had 4 to pass that standard to be marketed, so the sharing 5 back and forth of test results would have ceased at 6 that point, unless a question was raised.</p> <p>7 Q Maybe I wasn't articulate in my question. 8 As you sit here today, you have no evidence that 9 Johnson and Johnson ever supplied the FDA with any 10 test results concerning the talc for the presence of 11 asbestos or tremolite after 1976?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q Correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A That is correct. That's not something we 16 would have shared, so I don't have that.</p> <p>17 Q After 1976, the FDA continued to ask 18 Johnson and Johnson whether there was any evidence 19 of asbestos in Johnson and Johnson talc products, 20 correct?</p> <p>21 A Yes. The topic of asbestos in cosmetic 22 talc has come up over the years from time to time.</p> <p>23 Q And even though you were asked after 1976, 24 you never supplied the FDA with any test results 25 related to the Johnson and Johnson talc concerning</p>

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<p>1 asbestos or tremolite after 1976, true?</p> <p>2 A That would be true because the only thing</p> <p>3 we would have had is a certificate of analysis that</p> <p>4 would have been said no asbestos detected.</p> <p>5 Q Are you sure about that?</p> <p>6 A To the best of my knowledge.</p> <p>7 Q Now, let's go back and let's make sure we</p> <p>8 are still on the same sheet of music, based on what</p> <p>9 you testified to so far today.</p> <p>10 What I'm going to do to make sure we</p> <p>11 are in agreement is I'm actually going to create a</p> <p>12 chart of everything you have identified and have you</p> <p>13 tell me whether that chart is correct or not so we</p> <p>14 have it all in one place. You got me?</p> <p>15 A Okay.</p> <p>16 Q Let me start with the first test you</p> <p>17 identified, which is the tab 1A, which is the</p> <p>18 Dartmouth test dated June 28, 1971. Do you see</p> <p>19 that?</p> <p>20 A Yes.</p> <p>21 Q And what they did in the Dartmouth test</p> <p>22 is they used an optical microscope and x-ray</p> <p>23 diffraction, correct?</p> <p>24 A Yes.</p> <p>25 Q And they said the purpose of the study was</p>	<p>1 the test revealed. Do you see that?</p> <p>2 A Yes.</p> <p>3 Q What I put for the first entry was the</p> <p>4 date, Dartmouth Reynolds, Miller, studies of ground</p> <p>5 products, using XRD, PLM and what the test revealed</p> <p>6 there were no amphibole or asbestos impurities were</p> <p>7 observed, correct?</p> <p>8 A Yes.</p> <p>9 Q We are on the same page?</p> <p>10 A Yes.</p> <p>11 MR. SMITH: Counsel, are we going to</p> <p>12 mark this as an exhibit?</p> <p>13 MR. PLACITELLA: I will when I'm done</p> <p>14 with it.</p> <p>15 MR. SMITH: Do you have a copy for</p> <p>16 me?</p> <p>17 MR. PLACITELLA: I'll give you a copy</p> <p>18 as I do it, yes.</p> <p>19 MR. SMITH: I can't have a copy?</p> <p>20 MR. PLACITELLA: I can't give you a</p> <p>21 copy. I'm going to keep adding to it. I'll be</p> <p>22 making copies. When I'm done I'll have it printed</p> <p>23 by the court and I'll give you a copy.</p> <p>24 Q The next test I have here is also in 1A</p> <p>25 and that's on the same next page and this is the</p>
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<p>1 to examine the difference in the talc products that</p> <p>2 were produced by various milling procedures,</p> <p>3 correct?</p> <p>4 A Yes.</p> <p>5 Q And this was done by Dr. Reynolds at</p> <p>6 Dartmouth?</p> <p>7 A On the bottom of the report it would say</p> <p>8 who did it.</p> <p>9 Q He looked at both talc ore and talc</p> <p>10 products, correct?</p> <p>11 A Here it says he looked at x-ray and</p> <p>12 optical studies in bulk samples.</p> <p>13 Q And as it related to asbestos on page 5,</p> <p>14 correct, and in number 5 he says, "No amphibole,</p> <p>15 garnet or asbestos impurities were observed during</p> <p>16 optical studies of the products." Correct?</p> <p>17 A Correct.</p> <p>18 Q I created here, to make sure we have this</p> <p>19 down, is the date of the test -- do you see it? On</p> <p>20 your look on your screen.</p> <p>21 A Yes.</p> <p>22 Q The exhibit number, which is your tab</p> <p>23 number, who did the test, the testing entity, the</p> <p>24 author, the recipient, the purpose, the test method,</p> <p>25 if it was shown, the mine, what was tested and what</p>	<p>1 July 7, 1971 Colorado School of Mines. Do you see</p> <p>2 that?</p> <p>3 A Yes.</p> <p>4 Q It talks about doing an x-ray diffraction</p> <p>5 analysis of the Vermont products. Do you see that?</p> <p>6 A Yes.</p> <p>7 Q And what they found was no</p> <p>8 anthophyllite --hold on for a second. What they did</p> <p>9 is they looked at Vermont talc product 344 L,</p> <p>10 correct?</p> <p>11 A Yes.</p> <p>12 Q And they ran x-ray diffraction and the</p> <p>13 conclusion was they found no anthophyllite and only</p> <p>14 minor amounts, below one percent of tremolite and</p> <p>15 actinolite, correct?</p> <p>16 A Yes.</p> <p>17 Q Can we go back to the chart? I put on the</p> <p>18 chart. Still under tab 1A, Colorado School of</p> <p>19 Mines. The report went to Dr. Ashton, correct?</p> <p>20 They used x-ray diffraction of Vermont talc and we</p> <p>21 should add no anthophyllite and only minor amounts</p> <p>22 (below one percent) of tremolite and actinolite were</p> <p>23 detected. Is that good? We are on the same page?</p> <p>24 A Yes, we are on the same page. The</p> <p>25 tremolite and actinolite should not in any way imply</p>

<p style="text-align: right;">Page 260</p> <p>1 asbestos, because they didn't classify. 2 Q Ma'am, they didn't classify it one way or 3 another, and I'm not going there, okay? 4 A Okay. 5 Q We agree they classify it as asbestos or 6 non asbestos? 7 A Correct. 8 Q The next tab I have, I believe from you, 9 from is 9A, and that's a report from Dr. Pooley, 10 correct? 11 A Yes. 12 Q And it talks about a report of 13 investigations of talc samples supplied by Johnson 14 and Johnson, and then lists laboratory code numbers 15 1 through 10, correct? 16 A Yes. 17 Q And it talks about the purpose, which was 18 they did an analysis to establish the presence of 19 asbestos fiber of the chrysotile or amphibole types, 20 correct? 21 A Yes. 22 Q They used an electron microscope and x-ray 23 diffraction, correct? 24 A Yes. 25 Q What they sampled, if you look on the</p>	<p style="text-align: right;">Page 262</p> <p>1 Q Windsor 66 Talc, correct? 2 A Yes. 3 Q And I took the quote directly from the 4 report. The samples 1-10 were found to be free from 5 chrysotile, with the exception of one small 6 chrysotile fibril. I should add in parenthesis, 7 can I put in just contamination after that? Would 8 that satisfy you? 9 A I prefer if you write considered 10 background contamination. 11 Q What did you want to put in there, Doctor? 12 A Considered background contamination. 13 Q We added the part about no diffraction 14 pattern. Is that fair? 15 A Yes. 16 Q Let's go to, I think the next one you have 17 is 9D. You also flagged 9C, but that's a repeat of 18 the earlier -- what we just went through, right? It 19 is the same document? 20 A Yes. 21 Q So now 9D is the report to Johnson & 22 Johnson Research Center, Examination of Baby Powder 23 for Johnson and Johnson by McCrone dated August 19, 24 1971. Do you see that? 25 A Yes.</p>
<p style="text-align: right;">Page 261</p> <p>1 front page, is Windsor 66 talc used in the 2 manufacture of Johnson's Baby Powder. Do you see 3 that? 4 A Yes. 5 Q And what they concluded, or Dr. Pooley 6 concluded, was the samples, 1 through 10, were found 7 to be free of chrysotile asbestos fiber, with the 8 exception of one small chrysotile fiber, and then he 9 goes on to say that that was probably, in his 10 opinion, from background. Is that fair? 11 A Not probably. That is considered 12 background contamination. 13 Q Then he goes on to say no diffraction 14 patterns were observed, which corresponds to 15 diffraction patterns for amphibole asbestos fibers, 16 right? 17 A Right. 18 Q Can we go back to the chart, please. 19 Under 9A we have Dr. Pooley, the 20 purpose I took straight from the report. Do you see 21 that? 22 A Yes. 23 Q They used an electron microscope, x-ray 24 diffraction, Windsor Mine, correct? 25 A Yes.</p>	<p style="text-align: right;">Page 263</p> <p>1 Q What they tested was Johnson's Baby Powder 2 from batch 344L, correct? 3 A Yes. 4 Q What they were looking for was, they say 5 determine whether asbestos was present in the 6 powder, correct? 7 A What was your question? I'm sorry. 8 Q Let me get it for you. What they used is 9 an optical microscope and an electron microscope, 10 correct? 11 A Yes. 12 Q What they concluded was no asbestos or 13 asbestiform materials were identified. Only one 14 fiber was observed, which could not be identified as 15 rolled or folded flakes, correct? 16 A Yes. 17 Q Can we go to the chart. On the chart 18 under 8-19-1971, 9D, we have the author, McCrone, 19 optical microscope, electron microscope, correct? 20 A Yes. 21 Q Johnson's Baby Powder, or JBP I put as an 22 abbreviation, batch 344L, correct? 23 A Yes. 24 Q And I put in quotes, no asbestos or 25 asbestiform minerals were identified.</p>

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<p>1 A Yes.</p> <p>2 Q Are we on the same page?</p> <p>3 A Yes.</p> <p>4 Q The next one I have is 27A. 27A was part</p> <p>5 of the cover letter that went to Johnson and</p> <p>6 Johnson -- I mean to the FDA from Johnson and</p> <p>7 Johnson on October 17, 1972, correct?</p> <p>8 A Can you tell me the tab again?</p> <p>9 Q Yes, Ma'am, 27b</p> <p>10 A 27 B, yes.</p> <p>11 Q Actually, I'm looking at the cover letter,</p> <p>12 which is I think just 27, October 17, 1972?</p> <p>13 A I got it, thank you.</p> <p>14 Q Okay.</p> <p>15 A Yes.</p> <p>16 Q And September 8, under A is a report from</p> <p>17 Sperry-Rand to Dr. Goudie, correct?</p> <p>18 A Yes.</p> <p>19 Q He says that what he was doing was</p> <p>20 defining the types of particles which I referred to</p> <p>21 as asbestiform and which more correctly should be</p> <p>22 called fiber form. Do you see that?</p> <p>23 A Yes.</p> <p>24 Q What he used in his testing method was</p> <p>25 x-ray diffraction and an SEM microscope, correct?</p>	<p>1 conclusion, right?</p> <p>2 A Yes.</p> <p>3 Q We are on the same page?</p> <p>4 A Yes.</p> <p>5 Q Okay. The next test I have is in 25C, and</p> <p>6 that's the October 27, 1972 report from the Colorado</p> <p>7 School of Mines Research Institute. Do you see</p> <p>8 that?</p> <p>9 A Yes.</p> <p>10 Q It talks about -- it was to Dr. Goudie,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q And it talks about defining the -- scratch</p> <p>14 that. Determining if serpentine, possible</p> <p>15 chrysotile present. Correct, for the purpose of</p> <p>16 determining if serpentine, possibly chrysotile is</p> <p>17 present?</p> <p>18 A Yes.</p> <p>19 Q They ultimately determined that, here it</p> <p>20 says, "It is probable that the contention that the</p> <p>21 talc samples contain about 3 percent chrysotile is</p> <p>22 mistakenly based on the magnitude of the 7A</p> <p>23 chlorite. If this is so, it could have been avoided</p> <p>24 by step scanning," correct?</p> <p>25 A Yes.</p>
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<p>1 A I don't see where it says that. Can you</p> <p>2 point that out, please?</p> <p>3 Q Sure. If you look on the second page, it</p> <p>4 talks about the scanning electron microscope and the</p> <p>5 x-ray analyzer. Do you see that?</p> <p>6 A Yes, I see that. Thank you.</p> <p>7 Q And what he says is, "Based on the work</p> <p>8 I've done with chrysotile from Johnson's mine Quebec</p> <p>9 form A and C in the drawing have characteristics</p> <p>10 that would indicate they could very well be</p> <p>11 chrysotile." Do you see that part?</p> <p>12 A Yes.</p> <p>13 Q Then he goes on to say, "At the end, the</p> <p>14 scanning electron microscope and x-ray dispersion</p> <p>15 and x-ray analyzer are not able to positively</p> <p>16 identify chrysotile or any form of asbestos.</p> <p>17 However, these tools are very able to identify fiber</p> <p>18 forms which may be asbestos." Correct?</p> <p>19 A Yes.</p> <p>20 Q Can we go back to the chart, please. Do</p> <p>21 you see on the chart we have the date, Sperry-Rand,</p> <p>22 to Dr. Goudie, the purpose, the fact they used SEM</p> <p>23 and XRD and then the quotes we just went over.</p> <p>24 Forms A and C could very well be chrysotile. Then I</p> <p>25 have an ellipsis, I skipped stuff, and then the</p>	<p>1 Q Can we go back to the chart, please. So I</p> <p>2 have under the 10-27, under 25C, use an x-ray</p> <p>3 diffraction, looking at the Johnson Baby Powder lots</p> <p>4 108 and 109T, the quote we just went over. Correct?</p> <p>5 A I can't see.</p> <p>6 Q "It is probable that the contention that</p> <p>7 the two talc samples contain about 3 percent</p> <p>8 chrysotile is mistaken?"</p> <p>9 A Yes, that is correct.</p> <p>10 Q The next one I have 25, the report from</p> <p>11 McCrone dated October 27, 1972. Examination of</p> <p>12 Johnson & Johnson Baby Powder given to Dr. Goudie,</p> <p>13 correct?</p> <p>14 A Yes.</p> <p>15 Q And what they used in this test was x-ray</p> <p>16 diffraction, a light microscope and an electron</p> <p>17 microscope, correct?</p> <p>18 A Yes. X-ray diffraction, light and</p> <p>19 electron, yes.</p> <p>20 Q And therefore, the conclusion states, "A</p> <p>21 few tremolite rods were observed in both samples.</p> <p>22 No chrysotile has been detected." Correct?</p> <p>23 A Yes.</p> <p>24 Q Can we go to the chart, please?</p> <p>25 A Can I just add right before that it says</p>

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<p>1 showed material to be substantially free of 2 asbestiform materials.</p> <p>3 Q Okay. I'll add that in. Shown to be 4 substantially free of asbestiform material. Right 5 after he says substantially free, he says a few 6 tremolite rods were observed in both samples. No 7 chrysotile has been detected. Correct?</p> <p>8 A Yes.</p> <p>9 Q That's now what is on the chart. Are you 10 good with that?</p> <p>11 A Yes.</p> <p>12 Q The next tab I have is the report from 13 Gordon Brown at Princeton concerning Johnson's Baby 14 Powder, lot 108T.</p> <p>15 MR. SMITH: What tab?</p> <p>16 Q Same thing, 25C</p> <p>17 A 25C.</p> <p>18 Q 25C. Are you with me?</p> <p>19 A There's attachment of three reports together.</p> <p>20 Q And what he did is he used x-ray 21 diffraction, correct?</p> <p>22 A Correct.</p> <p>23 Q What he concluded was no evidence of 24 chrysotile or tremolite was found in the x-ray data 25 outlined above, correct?</p>	<p>1 A I think the testing entity is College of 2 Cardiff.</p> <p>3 Q Can we add that in? Other than that, we 4 are good?</p> <p>5 A Yes.</p> <p>6 Q The next test I have was the test that was 7 run by you, Johnson and Johnson, analysis for 8 Johnson's Baby Powder for tremolite asbestos dated 9 September 8, 1972, correct?</p> <p>10 A Yes.</p> <p>11 Q And that was done by Dr. Schelz?</p> <p>12 A Yes.</p> <p>13 Q And he used x-ray diffraction with step 14 scanning, correct?</p> <p>15 A Yes.</p> <p>16 Q And he did the testing on the 108T and 17 109T. Is that correct?</p> <p>18 A Yes.</p> <p>19 Q What he concludes is --</p> <p>20 A Third to the last lie. Samples of Johnson 21 and Johnson Baby Powder do not contain tremolite 22 within the limit of detection.</p> <p>23 Q Of the x-ray diffraction step scanning.</p> <p>24 Okay. Can we now go to the chart the for Schelz.</p> <p>25 Are you good with that, Doctor, the entry on 25C,</p>
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<p>1 A The conclusion is probably easier. It 2 says chrysotile and tremolite impurities proved 3 negative for the chart. If you go down on that page 4 to it is concluded. The last sentence.</p> <p>5 Q A careful search for chrysotile and 6 tremolite impurities proved negative.</p> <p>7 Are we good with that?</p> <p>8 A Yes.</p> <p>9 Q The next is that you identified was a 10 report from Dr. Pooley on those same sample lots, 11 correct, October 31, 1972?</p> <p>12 A Correct.</p> <p>13 Q And he, Dr. Pooley, used x-ray diffraction 14 and differential thermal analysis. Correct?</p> <p>15 A Correct.</p> <p>16 Q Are you with me? It is right on the front 17 page.</p> <p>18 A Yes, I got it.</p> <p>19 Q He says in his conclusion, "No chrysotile 20 is present in the samples of Johnson's Baby Powder 21 at the minimum level detectable by DTA." Correct?</p> <p>22 A Yes.</p> <p>23 Q Back to the chart. On the chart under 24 10-31-72, by Dr. Pooley, you agree with those 25 entries?</p>	<p>1 line 11, "The samples of Johnson's Baby Powder do 2 not contain tremolite within the limit of detection 3 of the x-ray diffraction step scanning technique?"</p> <p>4 A Yes.</p> <p>5 Q The next entry I have to look at is in tab 6 31, and that's under the cover letter of May 25, 7 1973. Are you with me?</p> <p>8 A Yes.</p> <p>9 Q And that attaches a report of baby powder 10 by Dr. Buerger -- I'm sorry, to Shower to Shower, 11 correct?</p> <p>12 A Yes.</p> <p>13 Q Dr. Buerger did x-ray diffraction 14 in his testing?</p> <p>15 A Yes.</p> <p>16 Q And he concludes at the end, "The 17 following impurities were determined not to be 18 present in detectable amounts. Chrysotile asbestos, 19 tremolite, antigorite, Musgravite (ph.), whatever 20 that is, fopcopite (ph.) quartz and dolomite." Got that?</p> <p>21 A Yes.</p> <p>22 Q On the bottom it says a little footnote 23 108T and 109T, correct?</p> <p>24 A Yes.</p> <p>25 Q Can we go to the chart under 5-25-73 and I</p>

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<p>1 have the report by Dr. Buerger using x-ray 2 diffraction, looking at Johnson's Baby Powder, 108T 3 and 109T and then the quote is directly from the 4 conclusion. Are you good with that? 5 A Yes. 6 Q The next one I have is under tab 36. 7 There's a report from Gordon Brown at Princeton 8 concerning Shower to Shower using x-ray diffraction, 9 correct? 10 A Correct. There was one before that, the 11 Buerger analysis. 12 Q Let's finish this one and we will go back. 13 A Okay. 14 Q This one says no evidence for chrysotile 15 or tremolite was found, fair? 16 A Yes. 17 Q Dr. Buerger was 31. Is that the one I 18 missed? 19 A Buerger, September 21, 1972. 20 Q What tab? 21 A I'm sorry. 36, right before the Gordon 22 Brown report. 23 Q October 7, 1972? 24 A Yes. 25 Q Are there actual results of testing here?</p>	<p>1 A Thank you. I was confused. The SPS, I 2 thought that was supposed to be XRD. I got the two 3 confused. 4 Q Now we are on this and we are talking 5 about the McCrone Shower to Shower report? 6 A Yes. 7 Q That was done by Dr. Stewart and they used 8 a number of methods, including XRD, TEM, PLM and 9 SEM, correct? 10 A Yes. 11 Q On page 6 of the report, as support for 12 their conclusions, they quote from a report from 13 Sperry-Rand and one from the University of 14 Minnesota. Do you see that? 15 A Yes. 16 Q What they conclude says, "An extensive 17 examination of samples of Johnson and Johnson 18 product, Shower to Shower using x-ray diffraction, 19 light microscopy, scanning electron microscopy, 20 transmission electron microscopy and electron 21 diffraction, has shown this product is free from 22 asbestos or asbestiform minerals. I report that 23 chrysotile was present in a sample from the batch 24 1501Z was erroneous and most likely a 25 misidentification for a form or quota." Do you see</p>
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<p>1 I didn't see them. 2 A I think you just re-reviewed Lewin's data. 3 Q But no new testing? 4 A I'm checking. This is a review of the 5 other data. It is not additional data. You are 6 correct. 7 Q Can we go back to tab 36. I want to 8 finish all this before lunch. I promise. Hopefully 9 this afternoon will be less boring. 10 Can we go back to tab 36? Can we go 11 to the chart, please. On 36, 11-9-73 by Brown, 12 x-ray diffraction of Shower to Shower. "No evidence 13 for chrysotile or tremolite in Lewin sample was 14 found," fair? 15 A Yes. 16 Q The next report I have, still under 36, is 17 a June 22, 1973 report from McCrone about Shower to 18 Shower, correct? 19 A Can we go back one second to the Princeton 20 results? 21 Q Sure. 22 A On the chart. 23 Q Which Princeton results? 24 A The ones we just put into the chart. 25 Q Okay. Go ahead.</p>	<p>1 that? 2 A Yes. 3 Q Can we go to the chart, please. On the 4 chart I have the tab 36, they used XRD, TEM and PLM, 5 SEM of Shower to Shower, right? Rather than do the 6 whole thing I just wrote quote Sperry-Rand and 7 University of Minnesota as negative test, correct? 8 A I'm not sure that's quite right. I think 9 what they are saying is scanning electron microscopy 10 is not an appropriate test. 11 Q Can I just say quote Sperry-Rand and 12 University of Minnesota and leave it at that? 13 A If that's of some value. 14 Q I want to come back to that. 15 Then I went right to the conclusion 16 and took the quote from the conclusion, an extensive 17 examination of the samples has shown. Do you see 18 that? 19 A Yes. 20 Q You are good with that? 21 A Yes. 22 Q The very next page is September 7, 1972, 23 test result from the Colorado School of Mines 24 Research Institute. Got it? 25 A Yes.</p>

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<p>1 Q They used x-ray diffraction, looking at 2 Shower to Shower, correct? 3 A Yes. 4 Q And what they said was, "The above data 5 does not indicate the presence of chrysotile." 6 Correct? 7 A Yes. 8 Q Can we go to the chart, please. Does this 9 accurately reflect what we just went through? 10 A Yes. 11 Q Now, lastly in this group, actually two 12 more, there is a test from Dr. Pooley sent to Dr. 13 Goudie dated September 29, 1972, correct? 14 A Yes. 15 Q And they looked at Shower to Shower? 16 A Yes. 17 Q And Dr. Pooley actually doesn't give any 18 results, right? What he says is, "The positive 19 identification of chrysotile can only be made with a 20 transmission electron microscope because it is with 21 this instrument that the fiber can be observed and 22 defined." Correct? 23 A Yes. 24 Q Can we go to the chart, please, under 25 9-29-72 for Dr. Pooley. Does that accurately</p>	<p>1 Q And you used x-ray diffraction? 2 A Yes. Differential thermal analysis. 3 Q Differential thermal analysis, and your 4 conclusion was what? 5 A No chrysotile detected in Shower to 6 Shower. 7 Q Can we go to that and make sure we have it 8 as Dr. Nicholson stated. 9 A I'm reading this off of the paper, so I 10 don't think you need to quote me. 11 Q I want to make sure we get the quote you 12 want. 13 MR. SMITH: Objection. 14 A It says no chrysotile by DTA, there was no 15 chrysotile detected in Shower to Shower. 16 Q Okay. So let me go to -- 17 A There's the x-ray diffractometer scans of 18 Shower to Shower from the J & J results also say 19 absence of chrysotile in this talc. Because he used 20 two methods. 21 Q So we should make sure it says XRD and 22 what? 23 A On page 2 of the memo at the top it says 24 the continuous x-ray diffractometer scans of Shower 25 to Shower powder exhibited by Dr. Lewin indicate the</p>
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<p>1 reflect what we just went through? 2 A Yes, but that's not a result of a test. 3 It is an opinion about the method. 4 Q Is that good? 5 A Yes. 6 Q Under that same tab, 9-28-72 is a testing 7 result by Johnson and Johnson itself, correct? 8 A You skipped -- I'm a little confused. You 9 skipped the Carnegie Mellon letter. 10 Q Okay. Let's go through that. 11 A And I say that I don't think it is test 12 results, it is people commenting on Lewin's letter 13 was referencing. 14 Q What would you like me to put on the chart 15 for Carnegie Mellon? 16 A I think that Pooley results shouldn't be 17 on the chart. It is fine the way you put them in 18 now. Just as Dr. Lewin was wrong, so we can move 19 on. 20 Q We can skip it? That's no news. You 21 always thought he was wrong, right? 22 A Not what I thought. He was wrong. 23 Q 9-28-72 is the analysis of Shower to 24 Shower done by Johnson and Johnson, correct? 25 A Correct.</p>	<p>1 absence of chrysotile in this talc. This is evident 2 from the lack diffraction, blah, blah, blah. 3 There are saying they are confirming 4 by x-ray diffraction that there's no chrysotile and 5 then below the last three of lines it says by DTA 6 there's no chrysotile detected in Shower to Shower 7 powder at the proposed level of two percent by Dr. 8 Lewin. 9 Q So let's go to the chart and make sure we 10 have exactly what you want in the chart. Under 11 method it should say XRD and DTA? 12 A Yes. 13 Q And then we have down here the absence of 14 chrysotile in the talc. What else do you want? 15 A It says absence by x-ray diffractometer, 16 so XRD, absence of chrysotile. 17 MR. PLACITELLA: It is 12:30. Do you 18 want to break for lunch and we will finish up 19 whatever is need to? 20 THE VIDEOGRAPHER: The time is 12:35. 21 We are going off the video record. 22 23 (Luncheon recess taken) 24 25 THE VIDEOGRAPHER: The time is</p>

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<p>1 1:32 p.m. We are now back on the video record. 2 Counselors, you may proceed. 3 4 BY MR. PLACITELLA: 5 Q Doctor, I'm going to your tab 45. By the 6 way, do you know why there are like numbers missing 7 in this book? 8 A No, I don't. 9 Q Like there's no 51. So the record is 10 clear, not all the numbers are in here, 1 through 11 whatever? 12 A I never noticed that, but you are right, 13 there are missing tabs. 14 Q I wanted to make sure. So, I'm looking at 15 tab 45 that you flagged, which is a October 4, 1974, 16 letter from Schelz to Schultz at the FDA. This is 17 about results from round robin test, right? 18 A Yes. 19 Q Do you recall that the round robin tests 20 were actually blind tests that different companies 21 got to test methodology? 22 A Yes. 23 Q There's no indication here on this 24 particular document that what this refers to is 25 actually a Johnson and Johnson product, correct?</p>	<p>1 A Yes. The one addition is George Stadlin 2 from Bristol Myers was actually the chairman of 3 CTFA talc subcommittee. 4 Q And J & J was part of that, right? 5 A That is correct. 6 Q So where it talks here on the second page, 7 you pointed out to me Johnson and Johnson, 150 8 samples all done by Pooley, right? 9 A Yes. 10 Q Do you see that? 11 A Yes. 12 Q There's no product here specified as to 13 what exactly he was testing, right? 14 A That is correct. This is a summary of 15 what tests had been done. I believe that's what the 16 summaries of analyses were sent. I believe that's 17 what this letter refers to. 18 Q On this particular document we don't know 19 if any of these tests were of Johnson and Johnson 20 products, correct? 21 A It doesn't explicitly say that, but it 22 does imply that they are from Johnson and Johnson. 23 You are correct. It doesn't list the sample names 24 and pedigree of those samples. 25 Q I'm going to get to that. It doesn't give</p>
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<p>1 These were blind tests? 2 A I'm sorry, I didn't understand the 3 question. 4 Q Sure. Blind test, what happened with the 5 round robin, as I understand it, is there were a 6 select group of samples that were sent to various 7 people to do testing, including Johnson and Johnson. 8 They were blind. Nobody knew the source of the 9 samples, other than the person who was handing them 10 out. Are you with me? 11 A Yes. 12 Q So we can't tell from looking at this 13 report whether the test referred to here is actually 14 of a Johnson and Johnson product. 15 A I only see talcum powder number 3, so I 16 don't know the exact source of that powder. That's 17 correct. 18 Q If you figure it out at some point, I'm 19 happy to put it on the chart. Right now I'm going 20 to leave it off, if that's okay with you. 21 A That's fine. 22 Q The next tab I think these are all 23 related that you flagged was tab 52, and that was a 24 September 12, 1975 letter from Bristol Myers to the 25 FDA. Are you with me?</p>	<p>1 the method that was used to do the analysis here, 2 does it? 3 A No, it does not. 4 Q I think the answer is a little further 5 down. This talks about -- this particular document 6 talks about various attachments, including the 7 attachments from Johnson and Johnson, correct? 8 A Yes. 9 Q It says right underneath it, I have 10 included the attachments, right? 11 A Yes. They are in the subsequent tabs. 12 Q And then you have all the tabs that were 13 attachments, correct? 14 A Yes. 15 Q If you go to the attachment under I, 16 there's a May 20, 1975 letter from Pooley to Johnson 17 and Johnson, correct? 18 A Yes. 19 Q What he says is, "In reply to your 20 question concerning how many talc specimens we have 21 examined over the past few years, we have arrived at 22 the following figures," and he talks about getting 23 it from 30 different geographical sources, correct? 24 A Correct. 25 Q And he says, "If you put them all</p>

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<p>1 together, that would have come up with about 150 2 samples," right?</p> <p>3 A Correct.</p> <p>4 Q That's the same number that is in the 5 Bristol Myers Squibb letter, correct?</p> <p>6 A Yes, correct.</p> <p>7 Q Johnson and Johnson didn't get talc for 8 use in the United States from 30 different 9 geographical sources, correct?</p> <p>10 A Well, I can't answer that directly because 11 geographical sources could mean different areas of a 12 single mine or different areas of several mines.</p> <p>13 Dr. Pooley did a survey of both of 14 them, the Vermont mine and Italian mine. Maybe it 15 is referring to that.</p> <p>16 Q I think there's more information that will 17 help us through this.</p> <p>18 So then if I go to tab J, which is 19 the April 29, 1975 letter from Johnson and Johnson 20 to the CTFA, the man that wrote the letter at 21 Bristol Myers. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q What Johnson and Johnson says is, "Our 24 scientists and consultants have conducted numerous 25 studies on the purity level of cosmetic talc grades</p>	<p>1 A Not correct. Italy and the United States 2 are both listed here.</p> <p>3 Q You are right. I'm sorry.</p> <p>4 A We have a worldwide talc business, which 5 could have included mines in these other geographic 6 sites.</p> <p>7 Q But you weren't getting talc from Brazil 8 and putting it in talc that was sold in New Jersey, 9 right?</p> <p>10 A No.</p> <p>11 Q So then if we go to attachment B, which 12 was also referred to in your list, do you see Dr. 13 Pooley's summary report?</p> <p>14 A Yes.</p> <p>15 Q There's an attachment B. This is what 16 Pooley did, right?</p> <p>17 A Yes.</p> <p>18 Q And you remember in the original letter to 19 the FDA it referred to the results of Pooley, 20 correct?</p> <p>21 A Yes.</p> <p>22 Q Here we say if you want to go to Pooley's 23 report, go to attachment B, correct?</p> <p>24 A Yes.</p> <p>25 Q If I go to attachment B, Pooley states,</p>
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<p>1 from both domestic and worldwide sources." Do you 2 see that?</p> <p>3 A Yes.</p> <p>4 Q Then further down it talks about since 5 1972, and it talks about who did the test. Do you 6 see that?</p> <p>7 A Yes.</p> <p>8 Q And some of them include the entities that 9 we have gone through already today, Colorado School 10 of Mines, Professor Brown, Professor Buerger, 11 correct?</p> <p>12 A Yes.</p> <p>13 Q Then it says on the bottom, "Further 14 details of the country of origin and the method of 15 analysis are described in attachment A." Do you see 16 that?</p> <p>17 A Yes.</p> <p>18 Q Then if you go to attachment A, which is 19 tab K, it gives the country of origin and it lists 20 Italy, Indian, USA, Korea, Brazil, Australia, 21 Pakistan, China and Austria, correct?</p> <p>22 A Yes.</p> <p>23 Q Out of this entire list, the only mine 24 that potentially was a supplier for talc used in the 25 United States was Italy, correct?</p>	<p>1 "Over the past two years we have engaged in an 2 extensive study of samples of cosmetic talc from 3 various parts of the world." That's consistent, 4 correct?</p> <p>5 A Yes.</p> <p>6 Q And it says, "A number of these samples 7 are imported at regular intervals into the United 8 Kingdom," correct?</p> <p>9 A Yes.</p> <p>10 Q Samples have been received and examined 11 from the following countries. And here he lists 12 Italy, France, India, South Korea, China, Zambia, 13 Austria, Brazil and Pakistan, correct?</p> <p>14 A Yes.</p> <p>15 Q Again, on the next page he talks about the 16 talcs he is testing were used in the United Kingdom, 17 correct, and he actually states on the bottom, "The 18 mineralogical investigations have come up cosmetic 19 grade talc powders entering the United Kingdom has 20 not been confined to single batch samples. Many of 21 the patterns have been examined over a period of 22 time from independent shipments." Do you see that?</p> <p>23 A Yes.</p> <p>24 Q So Dr. Pooley's report is not about talc 25 that was used necessarily in the United States. It</p>

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<p>1 was talc that was used in the United Kingdom, right?</p> <p>2 According to his report. His report is all about</p> <p>3 stuff that was used in Great Britain.</p> <p>4 A That's what it says. They were used in</p> <p>5 the United Kingdom.</p> <p>6 Q So when you were referring in 52, when</p> <p>7 this letter talks about the samples done by Dr.</p> <p>8 Pooley, which he said were all negative for</p> <p>9 chrysotile?</p> <p>10 A Yes.</p> <p>11 Q What he was talking about was the samples</p> <p>12 that he looked at of talc that was used in the</p> <p>13 United Kingdom, right?</p> <p>14 A Yes.</p> <p>15 Q So in terms of testing that I'm going to</p> <p>16 put on the chart for talc that was used in the</p> <p>17 United States and sent to places like New Jersey,</p> <p>18 I'm not going to include that. Okay?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A So to go back to the list, Dr. Pooley was</p> <p>21 in the United Kingdom, so it makes sense he would be</p> <p>22 using cosmetic talcs shipped to the United Kingdom.</p> <p>23 I'm looking at the details in the</p> <p>24 context of your question, but we do have Italy and</p> <p>25 we know we sourced Italian talc in the U.S. and we</p>	<p>1 talc shipment is routinely examined for asbestos.</p> <p>2 The number of analysis appears low, however."</p> <p>3 Correct?</p> <p>4 A Yes. That's what it says.</p> <p>5 Q Then the next paragraph says, "Johnson and</p> <p>6 Johnson also reported the analysis of American and</p> <p>7 British talc products based upon a cooperative study</p> <p>8 between Dr. Langer and Dr. Pooley. This study</p> <p>9 involved 19 samples analyzed by Langer, of which ten</p> <p>10 samples were implicated to contain asbestos."</p> <p>11 Correct?</p> <p>12 A Yes.</p> <p>13 Q Can we tell from looking at this whether</p> <p>14 these were actually samples of Johnson and Johnson?</p> <p>15 A We don't know that for sure, but we know</p> <p>16 that Langer said they were Johnson and Johnson talc.</p> <p>17 Q Okay. And it says, "Wherever Langer</p> <p>18 reported tremolite and anthophyllite, Dr. Pooley only</p> <p>19 found anthophyllite." Correct?</p> <p>20 A Correct.</p> <p>21 Q And they go on to say, "That these tests</p> <p>22 were done on samples and done in 1973." Correct?</p> <p>23 A Yes.</p> <p>24 Q So if we were going to go to the chart and</p> <p>25 we were going to add this one, we would have</p>
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<p>1 also have U.S. sourced talc.</p> <p>2 Because it is used in the United</p> <p>3 Kingdom doesn't mean it is not relevant to the FDA.</p> <p>4 So whether you want to add it to your chart or not</p> <p>5 doesn't matter to me.</p> <p>6 Q All I want to try to put in the chart is</p> <p>7 tests that we know were done on cosmetic talc or the</p> <p>8 source that was definitely used in the United</p> <p>9 States. We can't say that for certain from all</p> <p>10 this. Do you agree?</p> <p>11 A That's true.</p> <p>12 Q Then the last reference you had was on tab</p> <p>13 56, and that was in a March 18, 1976 -- and that was</p> <p>14 actually a memo that was an internal memo at the</p> <p>15 FDA, correct?</p> <p>16 A That is correct.</p> <p>17 Q The subject is asbestos in talc, correct?</p> <p>18 A Proposed regulation, yes.</p> <p>19 Q Under Johnson and Johnson, it talks about</p> <p>20 tests that were done in 1972 and 1973. Did you see</p> <p>21 that using XRD?</p> <p>22 A Yes.</p> <p>23 Q And sometimes TEM, correct?</p> <p>24 A Yes.</p> <p>25 Q And what the FDA says is, "Allegedly every</p>	<p>1 3-18-1976, we would say Pooley and Langer, or do you</p> <p>2 want me to say as reported by? What do you want me</p> <p>3 to put as the source?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A At the source, meaning the source of the</p> <p>6 samples?</p> <p>7 Q Whoever did the test. Should we put</p> <p>8 Pooley and Langer?</p> <p>9 A Yes.</p> <p>10 Q Pooley and Langer, 1973, correct?</p> <p>11 A Correct.</p> <p>12 Q And I guess we will just quote it so it is</p> <p>13 clear, right? It says, "This study involved the 19</p> <p>14 samples analyzed by Dr. Langer, of which ten samples</p> <p>15 were implicated to contain asbestos. Wherever Dr.</p> <p>16 Langer reported tremolite and anthophyllite, Dr.</p> <p>17 Pooley only found anthophyllite."</p> <p>18 A It says Dr. Pooley did not find --</p> <p>19 Q I'm still going. "Dr. Pooley did not</p> <p>20 find asbestos in those samples where Dr. Langer</p> <p>21 determined asbestos at concentrations at less than 5</p> <p>22 percent i.e., Dr. Pooley implicated only five</p> <p>23 samples." Are we good?</p> <p>24 A I don't think this is clear at all. The</p> <p>25 next sentence says about British talc samples.</p>

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<p>1 Are they saying it was British talc samples in which 2 they thought they might have seen anthophyllite? I 3 think the results here are unclear. I do know that. 4 Q Why don't we put the whole quote in? 5 A You can put the whole thing in. I think 6 it is still not clear. 7 Q Anthophyllite is asbestos. We know that, 8 right? 9 A No, that's not true. 10 Q Not true? 11 A No. You can have non -- most of 12 anthophyllite is not asbestos. 13 Q But it doesn't say here one way or the 14 another? 15 A Exactly my point. 16 Q But what they were testing for was 17 asbestos, right, because the subject here is 18 asbestos in talc, right? 19 MR. SMITH: Objection. 20 A Correct, but to really understand the 21 context of this, it is important to know what Langer 22 found and Langer was with Pooley specifically as 23 they were determining what the appropriate methods 24 were. He was there basically learning from Dr. 25 Pooley.</p>	<p>1 never gave the FDA an asbestos test results 2 concerning the talc after 1973. 3 MR. SMITH: Objection. 4 A According to the records here, it does not 5 appear to be. I would like to look at the table 6 where you put all the dates in, please. 7 Q As soon as she is done typing we will go 8 through it. 9 A Whatever the last date on is on here I'm 10 not aware of communications with any other asbestos 11 testing done by Johnson and Johnson that was on 12 Johnson and Johnson's behalf given to the FDA. 13 Q When you want to see the next screen, let 14 me know. 15 A Go ahead. Go down. That's correct. 16 Q So Johnson and Johnson never provided the 17 FDA any asbestos test results on the cosmetic talc, 18 according to your records, after 1973. Correct? 19 A That is correct. 20 Q Now, I want to go back and I looked at 21 your notes and your other binders and I want to get 22 -- you keep talking about context. So I want to 23 talk about context of how and why these tests were 24 done, because I know you want to talk about that. 25 MR. SMITH: Objection.</p>
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<p>1 Q I get that. So should I take this off the 2 chart? I'll do whatever you want. Take it off the 3 chart all together or I'll write the quote in and 4 somebody will figure it out later. How is that? 5 MR. SMITH: Objection. 6 A You can do that. This is very unclear to 7 me. 8 Q While Carolyn is doing that, if I look at 9 all of the samples, and we have gone through 10 everything now, correct, everything you have tabbed? 11 A I believe so. 12 Q So if I look at all of the test results 13 that were provided to the FDA, it would appear that 14 there was no test result on Johnson and Johnson talc 15 that post dated 1973, correct? 16 A I would have to go back and look at the 17 list, but if I may, during this time much of this 18 analysis was around determining what the appropriate 19 methods were. 20 The J41 standard was being developed. 21 The FDA had proposed their standard, so -- 22 Q I get all that. All I'm asking you is the 23 following. From a review of the book and everything 24 we have gone through now for the better part of the 25 day, according to your records, Johnson and Johnson</p>	<p>1 Q Are you with me? 2 A I'm with you. I think it is important to 3 understand the information. 4 Q In your notes, and I think in the binder 5 you had, you had references to Johnson and Johnson's 6 involvement with Dr. Irving Selikoff and the Mt. 7 Sinai School of Medicine. Do you recall that? 8 A Yes, in the early '70s. 9 Q How that started was that there was a 10 publication by the Tenovus Institute in the open 11 medical literature that found talc in women's 12 ovaries and in the tumors in their ovaries, correct? 13 A I can't answer that directly because there 14 were several things going on at that time. I can't 15 say there was a cause and effect of that Tenovus 16 paper. 17 Q J10 is an article entitled Talc and 18 Carcinoma of the ovary and cervix from the Tenovus 19 Institute for Cancer Research. Do you see that? 20 A Yes. 21 Q You have seen this before, correct? 22 A Yes. 23 Q What happened here was they studied tissue 24 that was obtained from patients with cancer of 25 either ovary or the cervix. Correct?</p>

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<p>1 A Correct.</p> <p>2 Q In the results they said they didn't find</p> <p>3 any asbestos particles, but they did find talc in</p> <p>4 75 percent of the tumors that they looked at,</p> <p>5 correct?</p> <p>6 A Correct, and in approximately half of the</p> <p>7 normal tissue that they looked at.</p> <p>8 Q Okay. In the article they actually had</p> <p>9 pictures of the talc they found in the tumors,</p> <p>10 correct?</p> <p>11 A Correct.</p> <p>12 Q At the end of the article they -- scratch</p> <p>13 that.</p> <p>14 They also raise the issue of</p> <p>15 asbestos, although they didn't find any in this</p> <p>16 examination, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A They do write that in the paper in the</p> <p>19 discussion.</p> <p>20 Q Then what happens is that Johnson and</p> <p>21 Johnson goes to see Dr. Selikoff at Mount Sinai</p> <p>22 because of his reputation in the area, and asks for</p> <p>23 his help in actually looking at the tissue from</p> <p>24 these woman, correct?</p> <p>25 A That's correct.</p>	<p>1 Institute.</p> <p>2 Q It says Dr. Selikoff was prepared to help</p> <p>3 and you paid him, right?</p> <p>4 A I would assume so, yes.</p> <p>5 Q So he went to work for you.</p> <p>6 A I think that implies he would work for us</p> <p>7 as opposed to doing scientific work.</p> <p>8 Q Fair enough. And you define in your memo</p> <p>9 what exactly you are setting out to do. You say,</p> <p>10 "You should give serious considerations to</p> <p>11 initiating appropriate steps to developing</p> <p>12 scientific information and answer a number of</p> <p>13 questions raised, including whether talc does indeed</p> <p>14 get distributed in tissues of people using the</p> <p>15 products, and then assessing whether the talcs are</p> <p>16 of the type used in the pharmaceutical industry, and</p> <p>17 if so, are harmful to tissues." Correct?</p> <p>18 A Yes.</p> <p>19 Q Then it talks about paying Dr. Selikoff,</p> <p>20 right?</p> <p>21 A Yes.</p> <p>22 Q And copied on the memo to memorialize the</p> <p>23 meeting are a number of Johnson and Johnson key</p> <p>24 executives, correct?</p> <p>25 A Individuals from Johnson and Johnson. I</p>
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<p>1 Q When Johnson and Johnson went to see Dr.</p> <p>2 Selikoff, everything started out friendly, correct?</p> <p>3 A I wasn't there, but I assume so.</p> <p>4 Q They were there to get Dr. Selikoff's</p> <p>5 help, correct?</p> <p>6 A That is correct.</p> <p>7 Q And in this memo from April 30, 1971,</p> <p>8 which is up on the screen, it is actually a memo</p> <p>9 concerning the meeting with Dr. Selikoff, right?</p> <p>10 A Yes.</p> <p>11 Q And it talks about having the meeting with</p> <p>12 Dr. Selikoff and talking to him about actually doing</p> <p>13 work on what was found by the Tenovus Cancer</p> <p>14 Institute in Wales, correct?</p> <p>15 A Yes.</p> <p>16 Q It talked about the one of the reasons</p> <p>17 they went to see Dr. Selikoff is because of his</p> <p>18 expertise and his work with the American Cancer</p> <p>19 Society and his publications, correct?</p> <p>20 A Yes.</p> <p>21 Q And what ended up happening at that</p> <p>22 meeting is that Dr. Selikoff actually agreed to go</p> <p>23 to work for Johnson and Johnson, correct?</p> <p>24 A I wouldn't characterize it like that, but</p> <p>25 he did agree to look at tissues from the Tenovus</p>	<p>1 would not necessarily categorize them as key</p> <p>2 executives.</p> <p>3 Q Doctors, scientists, executives.</p> <p>4 A Scientists, research and development</p> <p>5 professionals.</p> <p>6 Q Fair enough.</p> <p>7 A And then, somehow, Johnson and Johnson</p> <p>8 obtained the actual tissue of these women from Great</p> <p>9 Britain and brought that to the United States.</p> <p>10 Correct?</p> <p>11 A I would disagree with the characterization</p> <p>12 of that. The Tenovus Institute agreed to</p> <p>13 collaborate and share their tissues. So Dr.</p> <p>14 Selikoff and Johnson and Johnson could also examine</p> <p>15 them.</p> <p>16 Q Right.</p> <p>17 A So we didn't somehow obtain them. It was</p> <p>18 a collaboration. Everybody was quite open about</p> <p>19 sharing the tissue.</p> <p>20 Q How did you get tissue from -- how did you</p> <p>21 get permission to look at tissue from these women's</p> <p>22 bodies? How did you get that?</p> <p>23 A I don't know what the process was in 1971,</p> <p>24 so I couldn't answer that specifically.</p> <p>25 Q Didn't you have to get permission from the</p>

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<p>1 women if you were going to look at what's in their 2 bodies?</p> <p>3 A I don't know what the process was in 1971 4 for obtaining consent from women. I'm sure the 5 folks at Tenovus followed whatever the appropriate 6 processes were.</p> <p>7 Q Then what happened was that, however you 8 got the women's tissue to the United States, you 9 made sure it was delivered to Dr. Selikoff, correct?</p> <p>10 A It may have been mailed directly to Dr. 11 Selikoff, but I know he received tissue from the 12 Tenovus Institute.</p> <p>13 Q That's like a lot of power, right? You 14 see tissue, talc in somebody's tissue in Great 15 Britain and then all of a sudden would you arrange 16 and have it in a hospital in the United States. I 17 couldn't do that, could I?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I would hope not. Because this is a 20 scientific exchange and this is common. If you have 21 something unusual it is very common to have another 22 laboratory, an expert in this case, the world's 23 expert, look at that tissue as well.</p> <p>24 Q He was the world's expert, correct?</p> <p>25 A At that moment in time in asbestos and</p>	<p>1 Q And to observe the preparation of the 2 tissue that was received from the Tenovus Institute 3 for an examination with electron microscope, 4 correct?</p> <p>5 A Yes.</p> <p>6 Q Someone from Johnson and Johnson was 7 actually there observing Dr. Selikoff do his 8 analysis, correct?</p> <p>9 A Yes.</p> <p>10 Q It says, "The subject of asbestos in 11 Johnson's Baby Powder from Dr. Langer's point of 12 view was also explored." Do you see that?</p> <p>13 A Yes.</p> <p>14 Q Then below it it talks about what Johnson 15 and Johnson observed. They observed the analysis of 16 the Tenovus samples, correct?</p> <p>17 A Correct.</p> <p>18 Q And the samples were prepared using the 19 method that are was used by Johnson and Johnson's 20 expert, Dr. Pooley, correct?</p> <p>21 A Correct.</p> <p>22 Q Then after they did this they actually put 23 the tissue under a microscope while Johnson and 24 Johnson was watching, correct?</p> <p>25 A That is correct.</p>
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<p>1 tissue, yes, he was.</p> <p>2 Q And when he looked at the tissue, he found 3 chrysotile asbestos in the tissue of the women that 4 you arranged to have examined by him, correct?</p> <p>5 A I'll disagree with your characterization. 6 Firstly, we didn't get the tissue from the women. 7 It was part of a study in the Tenovus Institute.</p> <p>8 And secondly I'm not aware that he 9 found chrysotile in that tissue, which was also 10 tested at Johnson and Johnson's labs, and there's a 11 lot more to the story than just Dr. Selikoff and 12 them examining the tissue.</p> <p>13 Q I'm going to get the whole story out. 14 That's my objective. If you think I'm missing 15 something, either you tell me or your lawyer will 16 bring it out. Can we agree?</p> <p>17 A Yes.</p> <p>18 Q J & J 17 is entitled, Meeting With Dr. 19 Langer on July 9th concerning Analytical Analysis of 20 Talc. Are you with me?</p> <p>21 A Yes.</p> <p>22 Q And it talks about Johnson and Johnson 23 visiting with Dr. Langer at Mount Sinai on July 9th, 24 correct?</p> <p>25 A Yes.</p>	<p>1 Q And then it says, "Viewing the grid 2 prepared on Friday, and it gives the magnification, 3 we were unable to find any particles which could 4 obviously be identified as talc. However, fibrous 5 structures were observed under higher magnification, 6 30,000 and up." Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Where it says we did this, it says, "These 9 fibers were identified by Dr. Langer as chrysotile." 10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q And it says, "Method of identification is 13 based upon his experiences in observing the fibers 14 of pure chrysotile under similar experimental 15 conditions. The characteristic density profile 16 across the diameter of the fibers is observed at 17 high magnification and indicates the presence of 18 tubular chrysotile." Do you see that?</p> <p>19 A Yes, I do.</p> <p>20 Q There's nothing in this memo where Johnson 21 and Johnson is taking exception to what is being 22 observed while they are standing there, correct?</p> <p>23 A I don't see that, no.</p> <p>24 Q And so with Johnson and Johnson standing 25 there while Dr. Langer is looking at the tissue</p>

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<p>1 samples, Dr. Langer identifies chrysotile asbestos 2 in the tissue samples of the women who were studied 3 at the Tenovus Institute, correct? 4 A It appears he has found chrysotile, but I 5 know Dr. Langer was not able to identify chrysotile 6 in other materials, so I don't know what kind of 7 follow up there was to this memo. 8 Q All I'm asking you about is this memo. 9 in this memorandum, written by Johnson and Johnson 10 they report while they were standing there, that Dr. 11 Langer found chrysotile asbestos in the tissue of 12 the women, correct? 13 A Yes. This says Dr. Langer appears to 14 think he found chrysotile. 15 Q It doesn't say appears to think he found. 16 It says, "were identified as chrysotile by Dr. 17 Langer." Correct? 18 A Correct. 19 Q And then it goes on to state that he also 20 used a light microscopy and an electron microscope 21 looking at Johnson's Baby Powder. Correct? 22 A Correct. 23 Q And what he found, in part, was fibrous 24 content that varied from sample to sample. That is 25 what you report, correct?</p>	<p>1 A That is correct. 2 Q And then in the conclusion, in the summary 3 that Johnson and Johnson writes, they state, "In the 4 uterus sample from Tenovus, chrysotile, rather than 5 talc, was found. 2, chrysotile is identified in the 6 electron microscope scope by it is characteristic 7 tubular appearance at high magnification." Did I 8 read that correctly? 9 A You did. 10 Q And then in the fourth paragraph you 11 state, "Electron microscopy at high magnification 12 shows a few fibers to be present in Johnson's Baby 13 Powder, which can be identified with chrysotile 14 asbestos, according to Dr. Langer. No 15 quantification was performed." Correct? 16 A That is what it says, yes. 17 Q And what happened next was that within a 18 couple of weeks Dr. Selikoff and Dr. Langer reported 19 what they found in the press, correct? 20 A I believe it was a different results they 21 reported in the press but, yes. 22 Q These are documents when we got from 23 Johnson and Johnson. I didn't go out and find them, 24 just so you know. 25 So in here I put up on the screen is</p>
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<p>1 A That's what he indicated he observed. 2 That's what is in the memo, correct. 3 Q And then it states that he used an 4 electron microscope with Johnson and Johnson 5 standing there, correct? 6 A Correct. 7 Q And that, "using the electron microscope, 8 Dr. Langer had demonstrated to me the presence of 9 some very fine fibers at moderately high 10 magnification which he identifies as chrysotile 11 material asbestos by the typical tubular appearance 12 of the fiber." Correct? 13 A Yes, I see that. 14 Q And there's nothing in this memo that 15 takes exception to that, correct? 16 A Not in this memo, but there's a lot of 17 information outside this memo that would call into 18 question Dr. Langer's abilities to identify 19 asbestos. 20 Q Ma'am, when Johnson and Johnson was 21 sitting there watching Dr. Langer do these tests, 22 and they reported it back to the executives at 23 Johnson and Johnson, nowhere in the memo did they 24 question the findings of Dr. Langer, correct? 25 MR. SMITH: Objection.</p>	<p>1 one of those press articles, correct? 2 A I don't know. One of which press 3 articles? 4 Q Articles that were collected by Johnson 5 and Johnson about statements that were made by Mount 6 Sinai or Dr. Selikoff in the press about what he 7 found. 8 MR. SMITH: Objection. 9 A About what he found. This is a separate 10 topic with Dr. Kretchmer in the Environmental 11 Protection Agency. 12 Q Okay. You are right. This is out of 13 context. I'll come back to this. 14 (Exhibit J&J-24) After Johnson and 15 Johnson watched Dr. Langer do his test, Dr. Langer 16 wrote to Johnson and Johnson on November 10, 1971 17 and said, "We found asbestos in the tissue that you 18 sent us." Correct? 19 A Yes. 20 Q And he said, "We also looked at your 21 samples and we determined that the talc was fibrous 22 and that was chrysotile in your baby powder." 23 Correct? 24 A Yes. 25 Q And that upset Johnson and Johnson very</p>

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<p>1 much, didn't it?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A I would say yes. They reacted to this</p> <p>4 because we know there was not asbestos in our</p> <p>5 talc.</p> <p>6 Q Johnson and Johnson 25 is a letter you</p> <p>7 sent back to Dr. Langer about the samples, right?</p> <p>8 A Yes. It appears to be.</p> <p>9 Q And you documented again that he said he</p> <p>10 found chrysotile asbestos, correct?</p> <p>11 A Could you highlight what you are referring</p> <p>12 to?</p> <p>13 Q Yes, Ma'am. You observed some chrysotile</p> <p>14 asbestos to be present in the tissue?</p> <p>15 A Yes. I see that.</p> <p>16 Q What you said to Dr. Langer was we don't</p> <p>17 think you should publish this material, correct?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A The essence of this letter appears more</p> <p>20 around the methods and what methods they used,</p> <p>21 trying to understand that.</p> <p>22 Q You state, "It suggests, therefore, that a</p> <p>23 publication of your observations are on potentially</p> <p>24 contaminated tissue may have limited scientific</p> <p>25 value."</p>	<p>1 A I don't recall that characterization.</p> <p>2 Q (J&J Exhibit-39). This is a November 29, 1972</p> <p>3 memo on Johnson and Johnson letterhead and it was to</p> <p>4 D.D. Johnston?</p> <p>5 A I see that.</p> <p>6 Q He was the president of the company at the</p> <p>7 time?</p> <p>8 A I didn't know that.</p> <p>9 Q The subject is Antagonistic Personalities</p> <p>10 in the Talc Story in the U.S., correct?</p> <p>11 A Yes.</p> <p>12 Q And one of those antagonistic</p> <p>13 personalities was at one time your friend, Dr.</p> <p>14 Selikoff, according to this memo, correct?</p> <p>15 A That's what it says, yes.</p> <p>16 Q And you state that, "The start of the</p> <p>17 attack on talc originated in England at the Tenovus</p> <p>18 Research Institute in Cardiff where a technician in</p> <p>19 microscopy published a paper." Right?</p> <p>20 A Yes. That's what it says.</p> <p>21 Q That was the institute that you were</p> <p>22 working with, collaborating with, and now they are the</p> <p>23 attackers?</p> <p>24 MR. SMITH: Objection.</p> <p>25 A This is the paper that we started with,</p>
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<p>1 A That's what it says, yes.</p> <p>2 Q So you had issues. Your position was,</p> <p>3 well, maybe you found asbestos, but it is possible</p> <p>4 the tissue was contaminated to begin with. That was</p> <p>5 your position, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A No. I think the question was around</p> <p>8 scientific methods, and we asked actually that the</p> <p>9 tumor sample be returned so that further study could</p> <p>10 be done.</p> <p>11 Q You wanted to get the samples back once he</p> <p>12 told you that he found asbestos, right?</p> <p>13 A No.</p> <p>14 Q You asked him for the samples back?</p> <p>15 A Correct.</p> <p>16 Q And then you paid him \$1000, right?</p> <p>17 A We paid him for the research he did, yes.</p> <p>18 That's correct.</p> <p>19 Q Now, you were aware that Dr. Selikoff also</p> <p>20 served as an adviser to the FDA?</p> <p>21 A I was not aware of that, no.</p> <p>22 Q After Dr. Selikoff found what he found, he</p> <p>23 was labeled by you not as a friend anymore, but as</p> <p>24 the attacker, correct?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 the Henderson Paper that they published independently</p> <p>2 and then we collaborated to follow up and try to</p> <p>3 understand what their findings were and engaged</p> <p>4 Dr. Selikoff to look at tissue. (Exhibit J&J-10)</p> <p>5 Q Right. The Institute, the Cancer</p> <p>6 Institute that you started cooperating with now was</p> <p>7 part of the attack on you, Johnson and Johnson,</p> <p>8 right?</p> <p>9 MR. SMITH: Objection.</p> <p>10 Q According to this.</p> <p>11 A It says attack on talc, not Johnson and</p> <p>12 Johnson.</p> <p>13 Q Then it says, "In the USA the leading</p> <p>14 group who initiated the attack on talc is located in</p> <p>15 New York City and consists of the following," and</p> <p>16 then you list Dr. Selikoff, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I see that.</p> <p>19 Q In the next page on paragraph 6 you talk</p> <p>20 about, "Although the FDA tries to be impartial in</p> <p>21 matters concerning drugs and health, there's a Dr.</p> <p>22 Weisler of the Department of the FDA concerned with</p> <p>23 food and cosmetics who is seeking recognition within</p> <p>24 the FDA. He has retained a consultant, Dr. Lewin,</p> <p>25 an analytical chemist of New York University for</p>

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<p>1 studying commercial talc products and their possible 2 asbestos content. Dr. Weisler seems particularly 3 anxious to condemn talc." Do you see that?</p> <p>4 A I see that.</p> <p>5 Q Dr. Weisler was the person who was working 6 at the FDA before your Dr. Ironman took his job, 7 correct?</p> <p>8 A I don't know what the sequence of events 9 were there.</p> <p>10 Q And Dr. Lewin was actually also a 11 scientist that was hired by members of your trade 12 institute, correct, before this time?</p> <p>13 MR. SMITH: Objection.</p> <p>14 A I believe he was hired by the FDA. I 15 don't recall that he worked for any organizations.</p> <p>16 Q You didn't know he was hired by Whittaker, 17 Clark and Daniels who supplied you with talc?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I don't recall that, no.</p> <p>20 Q So just to review for context, I think you 21 told us this last time, but just for context again, 22 what happened with Dr. Lewin was he was hired by the 23 FDA, and when he tested a whole host of talc, he 24 reported from his perspective that he had found 25 asbestos in Johnson's Baby Powder and Shower to</p>	<p>1 Q And the FDA agreed that they wouldn't let 2 the public see it until you had a chance to go over 3 it, correct?</p> <p>4 A I don't believe that's exactly what they 5 said, but it is common when results come in for a 6 given product that a company manufacturers, that 7 those results would be sent to them right away for 8 comments, consideration, awareness.</p> <p>9 Q I think you told me last time that you had 10 the relationship with the FDA. The FDA official 11 actually said this report will be released over my 12 dead body. Do you recall that?</p> <p>13 MR. SMITH: Objection.</p> <p>14 A I don't know what you mean we had a 15 relationship with them, and this comment that you 16 just made. I don't understand the connection. What 17 is the question?</p> <p>18 Q The FDA promised Johnson and Johnson that 19 that the report would not be released over the FDA's 20 official "dead body?"</p> <p>21 A That was an individual making a comment 22 from the FDA. I don't think that was a promise to 23 Johnson and Johnson.</p> <p>24 Q So you didn't think it was a promise when 25 you wrote it down in a memo and said that you were</p>
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<p>1 Shower, correct?</p> <p>2 A Yes. He reported numerous samples where 3 he found asbestos and later retracted those results.</p> <p>4 Q We are going to get to that.</p> <p>5 I think we discussed last time that 6 Johnson and Johnson actually received an advanced 7 report of the Lewin results before it was ever made 8 available to any member of Congress or any doctor, 9 correct?</p> <p>10 A The FDA, yes, they did send us a copy of 11 the report before any other communications were 12 made.</p> <p>13 Q Johnson and Johnson interceded with the 14 FDA and the FDA promised Johnson and Johnson it 15 would not release the Lewin report without Johnson 16 and Johnson's opportunity to review the report, 17 correct?</p> <p>18 A I don't know what you mean by interceded.</p> <p>19 Q You called them up and said please don't 20 release the report until we can look at it and give 21 our own comments, fair?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A I don't think that's correct. I think we 24 said we would like to look at that report before you 25 share it.</p>	<p>1 told that it wouldn't be released, but over the 2 FDA's official dead body? You didn't consider that 3 a promise?</p> <p>4 A No. That was a comment made by an 5 official at FDA.</p> <p>6 Q Is it fair to say that Johnson and 7 Johnson disagreed with Dr. Lewin's findings?</p> <p>8 A We did disagree and he later retracted 9 those results, as they were incorrect.</p> <p>10 Q I'm just asking you whether you disagreed 11 with the original findings.</p> <p>12 A Yes, we did.</p> <p>13 Q And what happened was in order to respond 14 to Dr. Lewin's results, you hired a number of 15 experts to look at the same samples, correct?</p> <p>16 A That is correct.</p> <p>17 Q And those were the experts that are on 18 this chart that we went through this morning, 19 correct?</p> <p>20 A That is correct.</p> <p>21 Q And, in fact, what the chart reflects 22 mostly is the experts that you hired to look at the 23 Lewin samples and what they found, correct?</p> <p>24 A The chart, yes. There were other -- the 25 FDA also hired an independent lab to look at those</p>

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<p>1 samples.</p> <p>2 Q I'm going to get to that. I promise.</p> <p>3 One of the experts, I think we went</p> <p>4 through them on the chart, that you hired, you,</p> <p>5 Johnson and Johnson, to refute the Lewin results,</p> <p>6 was the McCrone Institute, correct?</p> <p>7 A That is correct.</p> <p>8 Q And I think you testified last time</p> <p>9 Johnson and Johnson told the FDA McCrone never found</p> <p>10 asbestos in any material used to make Johnson's Baby</p> <p>11 Powder, correct?</p> <p>12 A Production material, that is correct.</p> <p>13 Q And that McCrone never found any form of</p> <p>14 asbestos in the source of talc used in Johnson's</p> <p>15 Baby Powder, correct?</p> <p>16 A What do you mean, the source of talc?</p> <p>17 Q The mines that were used to make the baby</p> <p>18 powder.</p> <p>19 A In the ore that comes out of the mines?</p> <p>20 Q Yes, Ma'am.</p> <p>21 A That's correct. We didn't find any</p> <p>22 asbestos in the ore that was used to make baby</p> <p>23 powder.</p> <p>24 Q Do you have in front of you the report</p> <p>25 that McCrone did on -- I'm just talking about baby</p>	<p>1 Q And is this the first time you have seen</p> <p>2 this report?</p> <p>3 A I may have seen it before, but not in</p> <p>4 preparation for this deposition.</p> <p>5 Q And in this report on page 2 there's a</p> <p>6 summary, correct?</p> <p>7 A Yes.</p> <p>8 Q And it actually reports the amount of</p> <p>9 tremolite that was found by McCrone, correct?</p> <p>10 A Correct.</p> <p>11 Q When it talks about total tremolite</p> <p>12 contents on the last page, it talks about .5 percent</p> <p>13 per 108T and about .2 to .3 for 109T, correct?</p> <p>14 A Yes.</p> <p>15 Q That's Johnson's Baby Powder, correct?</p> <p>16 A Correct.</p> <p>17 Q And down at the bottom it says, "A few</p> <p>18 tremolite rods were observed in both samples at a</p> <p>19 level less than .5 percent. No chrysotile was</p> <p>20 detected," correct?</p> <p>21 A Yes.</p> <p>22 Q That information never made it into the</p> <p>23 report that you sent to the FDA, correct?</p> <p>24 A That is correct.</p> <p>25 Q And Exhibit 34 is another version of the</p>
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<p>1 powder now. The report McCrone did on 10-27-72,</p> <p>2 25C? 25C is the 10-27-1972 report of McCrone</p> <p>3 concerning the examination of Johnson's Baby Powder,</p> <p>4 correct?</p> <p>5 A Correct.</p> <p>6 Q That's the report you gave to the FDA,</p> <p>7 correct?</p> <p>8 A In 1972, yes.</p> <p>9 Q Yes, Ma'am. And that report was the</p> <p>10 edited report. Can we agree on that?</p> <p>11 A I don't know that it is an edited report.</p> <p>12 Q You don't know that there were other</p> <p>13 versions of this report where the results were</p> <p>14 edited out and you gave a different report to the</p> <p>15 FDA? You never knew that?</p> <p>16 A I think every report undergoes editing.</p> <p>17 We have to look at that specifically to see exactly</p> <p>18 what you are referring to.</p> <p>19 Q Exhibit 36 is a report dated October 27,</p> <p>20 1972, examination of Johnson and Johnson Baby Powder</p> <p>21 by McCrone. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q And it says, "Do not use this report.</p> <p>24 Replaced by another version." Do you see that?</p> <p>25 A Yes.</p>	<p>1 report. Have you seen this version before?</p> <p>2 A I don't recall that I have.</p> <p>3 Q Do you see in this version under summary</p> <p>4 they crossed out the amount and instead they write</p> <p>5 in a few isolated crystals. Do you see that?</p> <p>6 A Yes.</p> <p>7 Q And then on the last page under results</p> <p>8 the total tremolite content is crossed out entirely.</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q And then on the bottom the levels are</p> <p>12 crossed out, correct?</p> <p>13 A Correct.</p> <p>14 Q What I put up here, 479, just so the</p> <p>15 record is clear, shows the original of the</p> <p>16 information on light microscopy from the original</p> <p>17 report and the edited report. Do you see that?</p> <p>18 A Yes.</p> <p>19 Q Did you ever see this before?</p> <p>20 A Not this exact picture, no.</p> <p>21 Q The fact that there was tremolite in</p> <p>22 Johnson's Baby Powder, that was nothing new to</p> <p>23 Johnson and Johnson, right? Everybody in the</p> <p>24 company knew that already?</p> <p>25 MR. SMITH: Objection.</p>

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<p>1 A Tremolite is not asbestos. Yes, people 2 were aware there's tremolite in talc. 3 Q Ma'am, that wasn't my question. Let me 4 ask it and we will fight over whether tremolite is in 5 asbestos or not before a jury. 6 All I'm asking you now is it was not 7 new news. Everybody knew there was tremolite in 8 Johnson's Baby Powder, correct? 9 MR. SMITH: Objection. 10 A Not correct. Everyone -- every person 11 obviously wouldn't know, and tremolite is not always 12 found in talc. 13 Q In front of you is Exhibit 26, and if you 14 go to the second page of 26, do you see where it 15 says, "Revised report, just received?" and it gives 16 the lot numbers? 17 A That's not what you just handed me. 18 Q Turn it over. 19 A Got it. Sorry. 20 Q It says, "Revised report just received" 21 108T and 109T, correct? 22 A Yes. 23 Q That's the McCrone report, right? 24 A I have to look at the date. It says on 25 the front, McCrone.</p>	<p>1 you, Johnson and Johnson, were aware that those 2 samples may not even be representative of Johnson 3 and Johnson talc, correct? 4 MR. SMITH: Objection. 5 A No. 6 Q You, Johnson and Johnson, actually were 7 happy that the Lewin samples were sent out to the 8 FDA before you found actinolite in the Johnson and 9 Johnson Baby Powder, correct? 10 MR. SMITH: Objection. 11 A I don't know what you are referring to. 12 Q Did you know that Johnson and Johnson hid 13 from the FDA that they found actinolite in the talc 14 that was used to make baby powder right around the 15 same time that Lewin was doing all these tests? 16 MR. SMITH: Objection. 17 Q Did you know that? 18 A No. That sounds incorrect. 19 Q Okay. I'm trying to figure out why they 20 would do that. But let's see if we can figure that 21 out? 22 MR. SMITH: Objection. 23 Q 368. 368 is a memo from May 8, 1973, 24 entitled Personal, Dr. D. Petterson, the president of 25 the company, correct?</p>
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<p>1 Q Right. And who is Nashad? 2 A Nashad was a research and development 3 employee of Johnson and Johnson. 4 Q He wrote to Dr. Goudie. Who is Dr. 5 Goudie? 6 A I don't remember. Dr. Goudie is another 7 person at Johnson and Johnson. 8 Q He received a whole bunch of these tests 9 on this chart, right? 10 A Right. 11 Q And Nashad writes to Goudie, "I thought 12 tremolite was mistakenly identified in view of 13 similarity to..." and then it gives some name I can't 14 say. Can you say that name? 15 A Sesquictrate. 16 Q What he writes side back is, "There are 17 trace quantities present confirmed both by McCrone 18 and Bill Ashton." Correct? 19 A Yes. 20 Q This is not new, correct? 21 MR. SMITH: Objection. 22 A Yes. 23 Q Johnson and Johnson, when all this was 24 going on, and this testing was being done of the 25 Johnson Baby Powder samples, the Lewin samples,</p>	<p>1 A I don't know who was president at that 2 time. 3 Q It states that, "Your question this 4 morning was how did Lewin assay timing relate to 5 actinolite showings? Baby Powder lots 108T and 109T 6 were alleged to contain asbestiforms by Lewin. 7 They were produced on April 17 and 18, 1972. Talc 8 shipments checked by microscope here showed all lots 9 clean just prior to and right after that time." Do 10 you see that? 11 A Yes. 12 Q Then it says, "The first showing of 13 actinolite we know about is October 1972. The 14 indications are that things were in good shape when 15 Lewin picked up the above two lots for his assays." 16 Correct? 17 A That's what it says. 18 Q That was signed by W. A., William Ashton, 19 correct? 20 A Appears to be, yes. 21 Q So you never told the FDA, did you, that 22 while Dr. Lewin was running the tests, Johnson and 23 Johnson knew that there was actinolite in the source 24 of talc for its baby powder, correct? 25 A I didn't quite follow your question, but</p>

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<p>1 actinolite isn't asbestos and it was a conversation 2 about asbestos and baby powder. So I don't see the 3 relation of the two things.</p> <p>4 Q Ma'am, actinolite can be asbestos and it 5 cannot be asbestos. It depends on what the results 6 are, correct?</p> <p>7 A That is correct.</p> <p>8 Q And here it doesn't say whether it is 9 asbestos or not asbestos, correct?</p> <p>10 A It doesn't say it is asbestos. If it is 11 asbestos, you say actinolite asbestos.</p> <p>12 Q We are going to get to that.</p> <p>13 Here what is reported is that there 14 was actinolite in that the characterization by 15 Johnson and Johnson is we are in good shape because 16 that stuff never went to Dr. Lewin, right? That's 17 what the memo says?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A No. That is not what the memo says.</p> <p>20 Q Let's just read the memo for the record, 21 and somebody else will make that determination.</p> <p>22 It says, "The first showing of 23 actinolite we know about is October 1972. The 24 indications are that things were in good shape when 25 Lewin picked up the above two lots for his assays."</p>	<p>1 going to go to the end because I promised counsel we 2 are going to deal with some issues at the witness's 3 request?</p> <p>4 MR. SMITH: Yes.</p> <p>5 Q I wanted to shift focus for the remainder 6 of today to the Lewin tests related to Shower to 7 Shower. Okay?</p> <p>8 A Yes.</p> <p>9 Q I promise you I'm not done. I know you 10 have a lot more to tell us.</p> <p>11 What is G11? What is the ingredient 12 in G11 that you use in Shower to Shower? What is 13 that for?</p> <p>14 A I have no idea what that is.</p> <p>15 Q It is not a special designation for some 16 talc additive?</p> <p>17 A Not that I'm aware of. I don't know.</p> <p>18 Q You never heard the word G11 before?</p> <p>19 A Not that I recall, no.</p> <p>20 Q I think we went over this morning, but 21 to refresh, Johnson and Johnson cited the tests 22 that McCrone did to the FDA in support of its 23 position that there was no evidence of asbestos 24 in the Shower to Shower product, and that Dr. Lewin 25 was incorrect.</p>
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<p>1 That's what it says, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A That is what it says.</p> <p>4 Q Do you have any evidence, as you sit here 5 today, that Johnson and Johnson ever advised the FDA 6 that they knew there was actinolite in the Johnson's 7 Baby Powder?</p> <p>8 A No, because actinolite isn't asbestos.</p> <p>9 There would have been no reason to tell them that.</p> <p>10 Q Let me ask you the question again, please.</p> <p>11 As you sit here today, do you have any evidence to 12 indicate that Johnson and Johnson ever told the FDA 13 that they knew there was actinolite in Johnson's 14 Baby Powder? Yes or no?</p> <p>15 A No.</p> <p>16 MR. PLACITELLA: Let's take a break.</p> <p>17 THE VIDEOGRAPHER: The time is 2:48.</p> <p>18 We are going off the record. 19 (Recess taken)</p> <p>20</p> <p>21 THE VIDEOGRAPHER: The time is 22 approximately 3:02. We are now back on the video 23 record. Counsel, you may proceed.</p> <p>24</p> <p>25 MR. PLACITELLA: We are probably not</p>	<p>1 Is that fair?</p> <p>2 A I believe that's correct, yes.</p> <p>3 Q In the context of these cases, we sent 4 subpoenas out to McCrone for their records. Have 5 you looked at McCrone's internal records related to 6 the testing of the Shower to Shower product?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A I have not.</p> <p>9 Q 376, the second page is a draft of notes 10 that were produced by McCrone with the Bates number 11 from this case. Do you see it in the lower right 12 hand corner?</p> <p>13 A Yes.</p> <p>14 Q The date of this is 11-11-71. The draft 15 is to Dr. Goudie at Johnson and Johnson and it 16 relates to medicated powder and Shower to Shower.</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q As it relates to Shower to Shower, there's 20 a section with a big X through it. Do you see that?</p> <p>21 A Yes.</p> <p>22 Q It says, "The Shower to Shower appeared to 23 have a few more fibers than the other two samples. 24 However, I think that might be due to possible 25 contamination from the G11. In the G11 we did find</p>

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<p>1 two positively identified chrysotile fibers and some 2 other fibers which, at first glance, appeared to be 3 chrysotile when you look at the electron diffraction 4 patterns. I believe that most of the fibers in the 5 Shower to Shower, which are suspect, may come from 6 G11."</p> <p>7 Did you ever see this before? 8 MR. SMITH: Objection.</p> <p>9 A No.</p> <p>10 Q I guess this wasn't shared with you in 11 preparation for your deposition?</p> <p>12 A No. This is a McCrone document. I 13 wouldn't have seen it.</p> <p>14 Q Then it says on the bottom, this is from 15 McCrone now, "I left out the comments on G11 from 16 the report because I felt you might want to change 17 your supplier or investigate your supplier. And 18 this would only tend to, and then I guess there's a 19 line, perhaps confuse the issue with the FDA." Do 20 you see that?</p> <p>21 A I do.</p> <p>22 Q So, is this the first time you found out 23 that McCrone purposely kept information on 24 chrysotile findings in Shower to Shower from the 25 FDA?</p>	<p>1 A I don't know. I don't know what G11 is. 2 I really have no idea.</p> <p>3 Q 485 are other handwritten notes that were 4 obtained from McCrone, and these notes are entitled 5 Transmission Electron Microscope, Hutchinson, 6 University of Minnesota. Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Have you ever seen these notes before?</p> <p>9 A No.</p> <p>10 Q They were not shared with you in 11 preparation for your deposition?</p> <p>12 A No. The scope of the deposition was 13 communications between us and the FDA.</p> <p>14 Q The scope was what you knew about and gave 15 to the FDA and what you didn't give to the FDA. You 16 knew that, right? It wasn't just about what you 17 gave, it was about what you didn't give.</p> <p>18 MR. SMITH: Objection.</p> <p>19 A Communications related to asbestos testing 20 in our talc material.</p> <p>21 Q Do you see under the section on Lewin?</p> <p>22 A Yes.</p> <p>23 Q It talks about the TEM test and it says, 24 "Five fibrous particles were found which gave 25 electron diffraction pattern unmistakably chrysotile</p>
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<p>1 MR. SMITH: Objection.</p> <p>2 A I don't know what that is. I don't know 3 what G11 is. I can't comment on that.</p> <p>4 Q Do you think it is proper to just edit 5 parts out of reports because you are afraid of what 6 the FDA may think?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A No, and I'm not sure that's what this said 9 G11 could be a non production additive for a 10 product. I really don't know, so I wouldn't jump to 11 conclusions.</p> <p>12 Q Did you change your supplier after that so 13 you could get the asbestos out of the Shower to 14 Shower like McCrone said you should?</p> <p>15 A I don't know what G11 is.</p> <p>16 MR. SMITH: Objection.</p> <p>17 Q Who should we ask then? It is kind of 18 important.</p> <p>19 MR. SMITH: Objection.</p> <p>20 A I don't know what G11 is. McCrone did the 21 testing. Perhaps they have the answer.</p> <p>22 Q Who at job Johnson and Johnson should we 23 ask about G11, and what it was that was kept from 24 the FDA about G11? Who should we ask?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 asbestos." Do you see that?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A I do.</p> <p>4 Q Is this the first time you found out that 5 McCrone had in its files handwritten notes related 6 to what the University of Minnesota did where they 7 found asbestos in Shower to Shower?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A I don't think you can jump to that 10 conclusion from these notes.</p> <p>11 Q You see under the next section Shower to 12 Shower?</p> <p>13 A Yes.</p> <p>14 Q And do you see where it talks about clear 15 samples found of serpentine material which gave 16 perfect chrysotile patterns? Do you see that?</p> <p>17 A I do.</p> <p>18 Q Was this information ever transmitted to 19 the FDA?</p> <p>20 MR. SMITH: Objection.</p> <p>21 Q About Shower to Shower?</p> <p>22 A I don't know what these notes refer to.</p> <p>23 If you will recall, there were a number of samples 24 where chrysotile was actually added to the samples 25 to look at the sensitivity of different testing</p>

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<p>1 methods. So I think you can't jump to conclusions 2 about what this lab book actually reflects in terms 3 of testing. 4 Q Ma'am, there's nothing in these notes 5 about adding. Take a look. See if there's anything 6 in there about adding chrysotile to Shower to Shower 7 in these notes. 8 A What I see is it transmission electron 9 microscopy samples and the method for sample 10 preparation are not included in these notes. We 11 couldn't know that. 12 Q There's nothing in these notes to indicate 13 that somehow somebody added asbestos and then said 14 oh, yes, we found asbestos, right? 15 MR. SMITH: Objection. 16 A The methods are not included in the notes 17 you gave me, so we have no idea what these samples 18 are. 19 Q Let's go to the last page where they talk 20 about Shower to Shower. It says, "Total 21 concentration calculation (Shower to Shower). 22 Prints of micrographs were cut to estimate the 23 relative area of asbestos and talc. On both one 24 square contained incontrovertible asbestos." Do you 25 see that?</p>	<p>1 MR. SMITH: Objection. 2 A Based on what you have given me, I don't 3 think this says they found asbestos in the samples. 4 You haven't provided the full document. 5 Q Ma'am, I provided the full document that 6 was given to us by McCrone. You have never been 7 provided this document before this very minute, 8 correct? 9 MR. SMITH: Objection. 10 A That is correct, but this document is 11 incomplete. I don't think you can jump to 12 conclusions based on this partial experimental 13 document. 14 Q This document was never shared with you 15 before this very minute, correct? 16 A That is correct, and it looks like a 17 partial document. There's important parts of this 18 that are missing. 19 Q You see at the bottom where it is actually 20 signed off on at the end of the document? 21 A Yes. When you do a lab book like this, 22 the pages are numbered. There are no numbers on 23 these pages. Is this two pages of ten or fifteen or 24 how many? It doesn't say. 25 Q The person who did the test signed off on</p>
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<p>1 MR. SMITH: Objection. 2 A That's what it looks like. 3 Q Anything in there about adding asbestos to 4 the baby powder? 5 A Again, you have not included the methods 6 for how these samples were prepared. You can't jump 7 to the conclusion you are jumping to. 8 Q I'm not concluding anything. I got this 9 document from McCrone. By the way, where are these 10 micrographs? That would tell us the story, wouldn't 11 it? 12 MR. SMITH: Objection. 13 A I've not seen these partial notes before 14 and the micrographs aren't included, nor the methods 15 included in what you gave me. 16 Q Well, where are the micrographs? 17 MR. SMITH: Objection. 18 A You provided me. I would ask you where 19 the micrographs and the information about how these 20 examples were prepared. 21 Q If you get a test result that finds 22 asbestos in your baby powder, wouldn't you save the 23 samples and the micrographs? 24 MR. SMITH: Objection. 25 Q Wouldn't that be normal procedure?</p>	<p>1 the test at the end, correct? That's the signature? 2 A I don't know this is the end. You don't 3 know if this is page nine of ten or where are the 4 other pages? 5 Q Why don't we do this because we are not 6 going to finish this time. Why don't you go back 7 and find it and tell me where the rest are, okay? 8 MR. SMITH: Objection. 9 A This is not a J & J document. It is from 10 McCrone. We wouldn't have the source documents. 11 Q They worked for you. Why wouldn't they 12 give you the source documents? 13 MR. SMITH: Objection. 14 A You provided the document. 15 Q Well, you know that the University of 16 Minnesota took this document, this base document and 17 turned it into a formal report that they gave to 18 you, right? 19 MR. SMITH: Objection. 20 Q You know that, right? 21 A No, I don't know that. I haven't seen 22 that report. 23 Q Ma'am, as you sit here today in preparing 24 for today's deposition, about what was given and not 25 given to the FDA, you have no idea that the</p>

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<p>1 University of Minnesota did a full report on what 2 they found in Johnson's Baby Powder? 3 MR. SMITH: Objection. 4 A I don't recall seeing a report from the 5 University of Minnesota. 6 Q Exhibit 33 is a report from the University 7 of Minnesota Space Science Center. Have you ever 8 seen this before? 9 A I might need a minute to look at. 10 Q Please take your time. 11 A It doesn't look familiar. 12 Q Please take your time. 13 A I may have seen this. I didn't review it 14 in preparation for the deposition today. 15 Q Go to the first page. It is entitled 16 Investigation of Possible Asbestos Contamination in 17 Talc Samples. Do you see that? 18 A Yes. 19 Q It says, "Specimens of powdered talc were 20 received from Johnson and Johnson Company and 21 McCrone Associates." Do you see that? 22 A Yes, I do. 23 Q "Analysis of these samples using the 24 scanning electron microscope was requested in order 25 to determine possible content of fibrous chrysotile</p>	<p>1 asbestos in the Shower to Shower material and one 2 example was found in the Lewin material." Correct? 3 A Yes. 4 Q So he was apparently looking at both the 5 Lewin material and the material you, Johnson and 6 Johnson, gave them of Shower to Shower, correct? 7 A Yes. 8 Q And what he says on the very next page is, 9 "In figures 17 and 18, electron micrographs of the 10 transmission type show the typical stranded 11 appearance of chrysotile asbestos." Correct? 12 A Yes. I see that. 13 Q He goes on to state, "It is felt, 14 therefore, that chrysotile asbestos does exist in 15 the specimens of Shower to Shower and Lewin supplied 16 to this laboratory." Correct? 17 A Yes. 18 Q Then what he attaches are the actual 19 pictures of the photo micrographs that were 20 referenced in the notes that we just went through, 21 correct? 22 A I cannot make a connection between the 23 document you gave me and these figures. I don't 24 know that it refers to the same experiment. 25 Q Do you have any evidence as you sit here</p>
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<p>1 asbestos contaminated in the talc samples." Do you 2 see that? 3 A Yes, I do. 4 Q Do you see on the next page where they 5 talk about that they are looking at the Lewin Shower 6 to Shower materials? 7 MR. SMITH: Objection. 8 A Yes. 9 Q Do you see on page 3 they have the results 10 of what they did with the transmission electron 11 microscope? Do you see that? 12 A Yes, I do see that. 13 Q And the transmission electron microscope 14 is the microscope that Johnson and Johnson said was 15 the gold standard for finding asbestos in talc, 16 correct? 17 A Yes. 18 Q And what the author says here is that he 19 looked at a large number of grids and found numerous 20 examples of fibrous material. Correct? 21 A Yes. 22 Q He goes on to say, "Of the large number of 23 grids examined, three examples of fibers, which upon 24 examination by electron diffraction, could be 25 classified as likely candidates for chrysotile</p>	<p>1 today that you ever provided a copy of this report 2 to the Food and Drug Administration? 3 A I don't know that we did. I do see that 4 it looks like the purpose of this report had to do 5 with scanning electron microscopy versus x-ray 6 dispersion, versus transmission electron microscopy, 7 and I would have to look through the material to see 8 if this is referenced in some way during the 9 discussions of methods developed. 10 Q Respectfully I move to strike your answer. 11 My question was, do you have any 12 evidence, as you sit here today, that a full copy of 13 this report was ever provided to the FDA? 14 A That's a different question. 15 Q Yes, Ma'am. 16 A A full copy of this report, no, or I would 17 have seen it. Was the information transmitted in 18 some other context that I'm not aware of, no, I 19 can't answer. 20 Q You do know that what happened was that 21 McCrone, when they submitted their report to the FDA 22 that you did give to the FDA, took edited pieces of 23 this report, selected pieces to suit its needs, 24 right? That's what happened. 25 MR. SMITH: Objection.</p>

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<p>1 A I don't know that's what happened, no.</p> <p>2 Q You have tab 36. Tab 36 is the report</p> <p>3 from McCrone dated June 22, 1973 related to Shower</p> <p>4 to Shower. Do you have that in front of you?</p> <p>5 A My tab 36 is a letter to Dr. Schaffner at</p> <p>6 the FDA. In here there's a report. Let me dig</p> <p>7 through here.</p> <p>8 Q The letter attaches the McCrone report.</p> <p>9 A I'm looking here. There are several</p> <p>10 reports. I got it.</p> <p>11 Q And this is the report that McCrone and</p> <p>12 Johnson and Johnson told the FDA that an extensive</p> <p>13 examination of the samples found no asbestos,</p> <p>14 including TEM, correct, and no chrysotile, right?</p> <p>15 A That is what it says.</p> <p>16 Q And if I go to page 6 of the report, you</p> <p>17 actually quote from the Hutchinson report, right?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A Yes, I see that.</p> <p>20 Q Are you with me now?</p> <p>21 A I am.</p> <p>22 Q And the Hutchinson report, you take to the</p> <p>23 FDA and you actually quote from J & J 33, correct?</p> <p>24 A Yes.</p> <p>25 Q And you start out quoting the conclusion</p>	<p>1 those documents.</p> <p>2 Q You are referring to 49, and I want to put</p> <p>3 that up. This is what you were referring to, where</p> <p>4 it says original?</p> <p>5 A Yes.</p> <p>6 Q The part I'm assuming that you are</p> <p>7 referring to is the very end which talks about</p> <p>8 chlorite?</p> <p>9 A Yes.</p> <p>10 Q Do you see here that's not talking about</p> <p>11 the Lewin report, right? That's talking about a</p> <p>12 sample and the batch number 1501Z, correct?</p> <p>13 A I'm trying to cross reference the various</p> <p>14 things here and again, I'm not an expert in chlorite</p> <p>15 versus asbestos and chrysotile, so I'm doing my best</p> <p>16 to cross manage.</p> <p>17 Q That's not the issue, Ma'am. When it</p> <p>18 talks about chlorite, it is referring to a specific</p> <p>19 example, 1501Z, correct, not the Lewin samples,</p> <p>20 correct?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A I don't know that that's not a Lewin</p> <p>23 sample. That's what I'm trying to figure out.</p> <p>24 Q Ma'am, that same statement is in the</p> <p>25 report that you gave to the FDA. That is nothing</p>
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<p>1 from the report. It says, "The extensive</p> <p>2 investigation reported here must conclude," right?</p> <p>3 A Yes.</p> <p>4 Q You have ellipses in your report, right,</p> <p>5 meaning stuff taken out?</p> <p>6 A Yes.</p> <p>7 Q And the stuff you took out was about</p> <p>8 Hutchinson's findings of asbestos, right.</p> <p>9 A Yes.</p> <p>10 MR. SMITH: Objection.</p> <p>11 A You hand me another document which refers</p> <p>12 to those results and it says that the original</p> <p>13 reports of chrysotile were erroneous and a</p> <p>14 misidentification of chlorite. Perhaps that's why</p> <p>15 they took that out of the report.</p> <p>16 Q What you did is, and we are going to get</p> <p>17 to that, what you did is, and that's why I handed it</p> <p>18 to you so we would have the whole truth here, is</p> <p>19 that you didn't give the FDA the report. You edited</p> <p>20 out the parts about asbestos, right? That's what</p> <p>21 you did?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A No. From what you just handed me it looks</p> <p>24 like those were incorrect results and those were</p> <p>25 chlorite. I haven't had a chance to review all</p>	<p>1 new, right?</p> <p>2 MR. SMITH: Objection.</p> <p>3 Q That conclusion is what you gave to the</p> <p>4 FDA?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A Yes.</p> <p>7 Q What you didn't give to the FDA, and what</p> <p>8 you edited out of the report you gave to the FDA</p> <p>9 were the findings by Hutchinson of chrysotile</p> <p>10 asbestos in your baby powder, correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 Q You didn't give that.</p> <p>13 MR. SMITH: Objection.</p> <p>14 A No, we didn't because in this document you</p> <p>15 just gave me, and I did find 1501Z. This is listed</p> <p>16 in the samples. It is the same batch as Lewin that</p> <p>17 there was mistakenly, and I'm not a microscopist,</p> <p>18 that they mistook chlorite for chrysotile.</p> <p>19 Q So it was the Lewin sample they made the</p> <p>20 mistake in? Is that your testimony?</p> <p>21 A Again, I'm not expert microscopist. I'm</p> <p>22 reading the document you put in front me. Page 3</p> <p>23 describes all the samples. 1501Z is the same sample</p> <p>24 batch that was examined by Professor Lewin. That's</p> <p>25 what it says.</p>

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<p>1 Q So when we go back to the Hutchinson 2 report, and it talks about looking at numerous 3 samples they talk about finding chrysotile in Shower 4 to Shower that was provided by both Lewin and 5 Johnson and Johnson, right? 6 MR. SMITH: Objection. 7 A Yes. 8 Q And nowhere did you disclose that 9 Hutchinson found chrysotile asbestos in the samples 10 you gave them that weren't Lewin samples, correct? 11 MR. SMITH: Objection. 12 A No. Not according to the document you 13 just gave me that says they mistakenly thought 14 chlorite was chrysotile. 15 Q Ma'am, you told me that was in the Lewin 16 sample. I'm asking you, you never told the FDA that 17 you have gave University of Minnesota other Shower 18 to Shower samples where they found chrysotile 19 asbestos. You never told them that, correct? 20 A Well, I don't know that that's true as I 21 haven't had the opportunity to cross check these 22 different documents on which samples they are 23 referring to. And again, this was a time when 24 people are making a lot of mistakes in 25 interpretation due to the lack of knowledge of</p>	<p>1 MR. SMITH: Objection. 2 A That's correct, because it appears they 3 had mistakenly identified chlorite as chrysotile. 4 Q In the handwritten notes -- scratch that. 5 J & J 58, have you seen this document 6 before, J & J 58? 7 A I may have. 8 Q What is your knowledge of J & J 58? 9 A I don't recall all the specifics, but I 10 see right up front there's the quantifying 11 asbestiform amphiboles in talc products. There was 12 some controversy over the methods used in grain 13 counting versus volume counting. 14 Q Can you tell me whether in J & J 58 it 15 talks about the purpose of the study dealing with 16 the concentration method? We did the last time, 17 correct? Do you remember we went through this? 18 A It may be two different things. The 19 concentration method versus concentration of 20 asbestos in talc materials. I think those are two 21 different concepts. 22 Q Do you recall we did this last time? I 23 don't really want to do this all over again. 24 Let me ask you this maybe I can 25 shortcut it. Do you have any record of this study</p>
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<p>1 methodology. 2 Q Ma'am, I respectfully move to strike that. 3 You never told the FDA that you gave 4 University of Minnesota samples of Shower to Shower 5 that weren't the Lewin samples where they found 6 chrysotile asbestos, correct? 7 A It appears so because that was not 8 chrysotile, it was chlorite, according to the 9 document you just showed me. 10 Q Move to strike, Ma'am. 11 When you sent the report to the FDA, 12 quoting Hutchinson, what you edited out was any 13 reference to asbestos, correct? 14 MR. SMITH: Objection. 15 Q That's what you did. 16 A That was left out of the report, yes. 17 Q And when you look at 478, I put side by 18 side, what you told the FDA on the top and what you 19 edited out on the bottom. Do you see that? 20 MR. SMITH: Objection. 21 A Yes. 22 Q What you edited out was transmission 23 electron microscopy showing less than one 24 hundreds of one percent asbestos in the material 25 given to us. That is what you edited out, correct?</p>	<p>1 done by Dartmouth ever being transmitted to the FDA? 2 A I don't think so. 3 Q I'm going to hand to you what's been 4 marked Musco-2. Do you know who Nancy Musco is? 5 A No. 6 Q Did you know she was somebody who 7 testified on behalf of Johnson and Johnson? 8 A No. 9 Q In this case? I'm going to show you 10 what's been marked Musco-2. You probably have to 11 move that. 12 MR. SMITH: Maybe I could see the 13 exhibit before you show it to the witness. 14 MR. PLACITELLA: Absolutely I'll do 15 that. No problem. 16 MR. SMITH: This is from the Musco 17 deposition? 18 MR. PLACITELLA: And others. 19 Off the video. 20 21 THE VIDEOGRAPHER: The time is 3:41. 22 We are going off the video. 23 THE VIDEOGRAPHER: The time is 3:45. 24 We are back on the video record. 25</p>

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<p>1 Q So you have in front of you first J & J 2 414. Do you see that? 3 A Yes. 4 Q I'll represent to you 414 was a chart that 5 was created, just like the chart we did today, at 6 the deposition of Dr. Hopkins. It took three days. 7 Have you had ever seen this chart before? 8 A No. 9 Q What we did is you can see the same exact 10 format. We went through all of the tests that were 11 produced and put the date, the exhibit number, the 12 testing entity, the author, the recipient, the 13 purpose, just like we did today. Do you see that? 14 A Yes. 15 Q For example, if you look at the entry for 16 3-9-71, for McCrone for Shower to Shower, it is the 17 same information we put on your chart. Do you see 18 that? 19 A Yes. 20 Q Just so I'm clear, no one ever shared this 21 chart with you before today? 22 A No. 23 Q And what you have is Musco-2 in front of 24 you? 25 A Yes.</p>	<p>1 the results, and I think there are a couple, you can 2 flip through it quickly, if you have any evidence 3 that you gave any of those results to the FDA at any 4 point in time? 5 MR. SMITH: Objection. 6 Q We can go off the video and you can take a 7 minute and we will figure out your other issue, 8 okay? 9 A I can't do this today. There are 370 10 documents here that I would have to look at and 11 cross reference them with other documents. 12 Q I promise that there's not 370. 13 A There are hundred 370 tabs. 14 Q There aren't. There are marks by exhibit 15 number. 16 A Missing numbers, missing tabs. 17 Q Just like before. 18 A I don't believe I can accurately answer 19 your question. 20 Q We know what you did provide. So all I 21 want to do is verify that you are didn't provide 22 anything that's in that book with one or two 23 exception. That's all and we will be done for the 24 today. 25 MR. SMITH: Objection.</p>
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<p>1 Q All the testing results that correspond to 2 that chart. If you want to look at it you can 3 verify the test. 4 A I see a big stack of paper here. I can't 5 verify that the chart is right. 6 Q Can you tell me from looking at Musco-2, 7 and we can take time and go off the video if you 8 want, which of the test results that are in Musco-2 9 Johnson and Johnson supplied to the FDA? 10 A Right off the top of my head I can't do 11 that, but I could provide context for why we sent 12 what we did send to the FDA. 13 Q All I want to know, Ma'am, we already did 14 that part. I want to know is in the book, Musco-2, 15 which are all the tests results we went over with 16 Dr. Hopkins, who you spoke to, correct? 17 A I have spoken to Dr. Hopkins, yes. 18 Q All the tests results we went over with 19 Dr. Hopkins, which of the test results that are in 20 Musco-2 did you provide to the FDA? That's all I 21 want to know. 22 A The results that we reviewed are on the 23 other table are the results that we supplied to the 24 FDA. 25 Q I want to just verify, Ma'am, if any of</p>	<p>1 A I'm not confident I can answer that 2 question accurately. 3 Q Let's put it this way. Anything in that 4 book that's after 1973 you didn't provide, right? 5 A That is correct. 6 Q So why don't you focus on the documents 7 for 1973 and before and tell me which ones you 8 provided. 9 A You want my opinion on why we wouldn't 10 wouldn't have provided these? 11 Q No, Ma'am. All I want to know is I just 12 am trying to get on the same page of what you gave 13 and what you didn't give. That is all I want do do 14 today. 15 MR. SMITH: If I might make a 16 proposal? 17 MR. PLACITELLA: To do what? 18 MR. SMITH: You got eight minutes 19 before we have got to get out of here. 20 MR. PLACITELLA: No, we have to get 21 out of here by 4:14. I promised I'll deal with your 22 issue. I would really like to get this on the 23 record before. 24 MR. SMITH: I thought you said you 25 wanted to be out of here by four o'clock.</p>

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<p>1 MR. PLACITELLA: I wanted to end by 2 four so I could deal with your issue. 3 MR. SMITH: I got you on that. To 4 end by four, we have eight minutes. 5 MR. PLACITELLA: Let's do our best. 6 The only thing she has to look at are documents 7 before 1973. Everything else, according to her 8 testimony, they never gave to the FDA. 9 MR. SMITH: I'm offering, and she is 10 going to come back. We know that. I could have her 11 look at this between now and then. If you want her 12 her to do it now, then you pick. 13 MR. PLACITELLA: I would like to 14 finish the record today. 15 MR. SMITH: I'm not sure you can. 16 MR. PLACITELLA: For this issue. 17 A Just in tab 9 there are multiple documents 18 in this tab, so I would have to turn page by page to 19 see what's actually here. 20 Q Okay. So I'll take your counsel's 21 suggestion so as to not labor and make you do this 22 here and now. 23 Is it fair to say, to close the 24 record for today, that if there's a test in there 25 that post dates 1973, based on the evidence you have</p>	<p>1 conversation outside how you want to deal with the 2 other issue. 3 THE VIDEOGRAPHER: The time is 4 approximately 3:54. This concludes today's video 5 deposition we are off the video record. 6 (The deposition is adjourned at 3:54 p m.) 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 before you, it was never provided to the FDA? 2 A Not under the umbrella of asbestos testing 3 of our talc products, no. 4 Q Now, is it a fair question to ask you 5 which of the test results in there you ever saw 6 before today? 7 A I would have to flip through the pages and 8 really look at it. 9 Q Is it fair to say that if the documents 10 are not on the chart, your chart from this morning, 11 which I'm going to mark right now, you didn't 12 provide them to the FDA? 13 A As far as I know, no, we didn't. 14 MR. PLACITELLA: What I want to do 15 now is I want to mark this collectively as P-6. 16 (The above document is marked 17 P-6.) 18 Q P-6 is the chart that we created this 19 morning, correct? 20 A It appears to be, yes. 21 Q And that's true and accurate, to the best 22 of your knowledge? 23 A At this moment as best as I can do, yes. 24 MR. PLACITELLA: Why don't we close 25 the record for today on that and let's have a</p>	<p>1 CERTIFICATE 2 3 I, MARC BRODY, Notary Public and 4 Certified Shorthand Reporter of the State 5 of New Jersey, do hereby certify that prior 6 to the commencement of the examination 7 the witness was duly sworn by me to 8 testify the truth, the whole truth and 9 nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a true and accurate transcript 12 of the testimony as taken stenographically 13 by and before me at the time, place and on 14 the date hereinbefore set forth. 15 I DO FURTHER CERTIFY that I am neither 16 a relative of nor employee nor attorney nor 17 counsel for any of the parties to this 18 action, and that I am neither a relative 19 nor employee of such attorney or counsel, 20 and that I am not financially interested in 21 the action. 22 23 24 Notary Public of the State of New Jersey 25</p>

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Exhibit 141

FDA-J&J Meeting
7/20/71

July 21, 1971

Special Talc Project No. 503
FDA Meeting, July 20, 1971

Dr. R. A. Fuller

Attendance:

FDA: Dr. R. Schaffner, Director, Office of Product Technology
Dr. L. Beacham, Dep. Dir., Office of Product Technology
Dr. A. Weissler, Director, Div. of Colors and Cosmetics
Technology
Dr. J. Gowdy (M.D.), Div. of Colors and Cosmetics
Technology
Dr. Eisenberg (microscopist)

J&J: Dr. G. Hildick-Smith, Dr. W. Nashed.

We reviewed briefly our official submission of July 20, 1971 (see attached letter). Dr. Schaffner signed our house copy acknowledging receipt.

We informed the group that, in addition to the work done by Colorado School of Mines Research Institute which showed that Baby Powder contains no asbestos, we have had Professor Pooley and the McCrone Associates and Johnson & Johnson laboratories do extensive examination of our talc and Baby Powder by electron microscopy. The results show that we have no asbestos in our product.

Dr. Weissler wanted to know if tremolite or fibrous talc was found. We stated that our information is that no asbestos was found and that we will have full detailed reports on the findings in about a week.

Dr. Hildick-Smith pointed out that Dr. William Smith's extensive work (10 years) under a PHS grant showed that tremolite talc did not produce tumors in animals while asbestos did. The information was included in our Exhibit 4.

Dr. Schaffner asked if we had been in touch with Dr. Selikoff to resolve the difference between his findings and ours. We said we plan to do so as soon as the reports of completed work is available.

Dr. R. A. Fuller

- 2 -

July 21, 1971

Dr. Schaffner said that his main mission at this time is to determine optimum methodology for examining talc samples. He asked Dr. Weissler to review his progress in this area. Dr. Weissler said that he had called Dr. Selikoff's office but that Dr. Selikoff was unavailable. He had also had the same experience in trying to contact Dr. Cralley (PHS Service, Cincinnati).

Dr. Gowdy raised the question of inhalation of fine particles of talc below 5 μ . He also said that there are cosmetic aerosol body powders and Dr. Schaffner asked for our particle size analysis of Baby Powder. We pointed out that our previous submission included particle size (by volume) analysis done by Colorado School of Mines and that we are currently preparing another report on particle size (in microns) of Baby Powder which would be submitted next week.

With regard to inhalation of fine inorganic particles, I pointed out that a farmer inhales a great deal of clay dust in his field throughout his life with no apparent danger and commented that if somebody was marketing clay Mr. Kretchmer would be asking FDA to ban it. This elicited amused smiles.

Dr. Eisenberg reviewed quickly the method supplied by Colorado School of Mines (Exhibit 2). He commented that he felt that the standard method followed by Colorado School of Mines using area % is a more valid procedure than electron microscopy.

Dr. Schaffner asked Dr. Weissler to set up a meeting, possibly Thursday of next week, with Dr. Selikoff and Dr. Cralley; also with our experts (Dr. Pooley, if available; Dr. McCrone; Mr. Caneer; and Dr. Rolle). He indicated that he has to give Dr. Edwards some recommendations in two weeks.

I told Dr. Schaffner that according to our previous discussion, we are supplying all our information to him and that he will coordinate dissemination of the information within the FDA. He agreed and said that they will also invite people from the Bureaus of Drugs and Product Safety to the discussion meeting to be set up by Dr. Weissler.

Finally, I stated that we have been doing a great deal of work without knowing precisely what Mr. Kretchmer's objections to talc were and that we can better direct our efforts if we know his specific objections. After some hesitation, Dr. Schaffner gave me a copy of Mr. Kretchmer's letter to the Secretary and a copy of the Kretchmer press release (see attached) and obtained my signature as a receipt on his copy.

Dr. R. A. Fuller

- 3 -

July 21, 1971

Actions:

We will provide FDA with:

1. Reports by Dr. Pooley, Dr. McCrone, and Johnson & Johnson on the results of electron microscopy examination of Baby Powder.
2. Report on particle size in microns of Baby Powder.
3. Convene our experts to meet with FDA at a date to be conveyed to us by Dr. Weissler.

W. Nashed

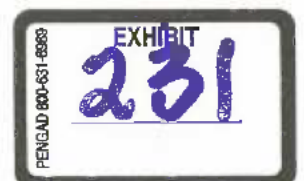
WN/cw

Attach.

cc: Mr. J. E. Burke
Mr. L. Foster
Dr. G. Hildick-Smith
Dr. T. H. Shelley
Mr. S. C. Smoyer
Mr. H. G. Stolzer to Mr. D. Clare
Mr. J. C. Walcott

Exhibit 142

J&J-FDA
9/21/71



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Johnson & Johnson

NEW BRUNSWICK, N. J.

September 21, 1971

R. Schaffner, Ph.D.
Director, Office of Product Technology
Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
200 "C" Street
Washington, D.C.

Subject: JOHNSON'S Baby Powder

Dear Dr. Schaffner:

My colleagues and I wish to express our thanks for your providing us the opportunity on August 3, 1971 to present our data and methods of testing of JOHNSON'S Baby Powder and the talc used in its manufacture.

As we discussed, we are submitting herewith full reports of our investigations as follows:

Identification of Samples used in the Pooley report and McCrone report.	Exhibit 1 [Vol. 1]
Letter from Colorado School of Mines Research Institute.	Exhibit 2 [Vol. 1]
Report by Johnson & Johnson Pharmaceutical Research Section: "Particle Size of JOHNSON'S Baby Powder."	Exhibit 3 [Vol. 1]
Report by Dr. F. D. Pooley, University College, Cardiff, Wales: "Report of Investigations of Talc Samples supplied by Johnson & Johnson."	Exhibit 4 [Vol. 1]
Reports by Walter C. McCrone Associates, Inc.:	Exhibit 5 [Vol. 2 - Vol. 3]
(a) "Methodology for the Determination of Asbestos in Talc."	
(b) "Examination of Baby Powder for Johnson & Johnson."	

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R. Schaffner, Ph.D.

- 2 -

September 21, 1971

It is seen that the data conclusively proves that JOHNSON'S Baby Powder is free of asbestos.

It is suggested in the interest of future references to this data that our filings of July 8 and July 20, 1971 as well as this filing be incorporated in a master file with a reference number which can be utilized in future communications on this matter.

Should you have any questions regarding the data submitted, we will be very pleased to answer them.

Thanks for your consideration.

Very truly yours,
JOHNSON & JOHNSON

W. Nashed

by: W. Nashed, Ph.D.
Director of Science Information

WN/cw

Attach: Vols. 1, 2, and 3

bcc: Mr. J. E. Burke
Mr. D. Clare
Dr. R. A. Fuller
Mr. L. Foster
Dr. G. Hildick-Smith
Dr. T. H. Shelley
Mr. S. C. Smoyer
Mr. J.C. Walcott

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The information and data submitted herein contains trade secrets, commercial or financial information or privileged or confidential information, and the Food and Drug Administration is not authorized to make them public without written permission from the company.

Exhibit 143

159468

Johnson & Johnson

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

Dr. N. F. Estrin
C.T.F.A.

-2-

March 15, 1976

March 15, 1976

Dr. Norman F. Estrin
Vice President - Science
Cosmetic, Toiletries, and
Fragrance Association
1133 15th Street, N.W.
Washington, D.C. 20005

Re: Examination for Asbestos In Talc

Dear Dr. Estrin:

The talc which is used by Johnson & Johnson is solely derived from its own mine in Vermont, where the ore is mined selectively and then beneficiated by the process of flotation.

Shipments of this highly purified talc are routinely examined by our own laboratory to verify the absence of asbestos minerals.

Historically, Johnson & Johnson has always been concerned about the mineralogical integrity of its talcs and even its earliest specifications have required the examination for acicular particulates. When it was erroneously reported in 1971 that our powder contained asbestos, we sponsored a scientific seminar of mineralogical and analytical experts for the FDA to prove that our talc is not contaminated with asbestos. At that time numerous samples were analyzed by experienced consultants such as McCrone Associates, Colorado School of Mines, Professor F. D. Pooley (of the University College, Cardiff), Professor G. Brown (of Princeton), and Professor M. Buerger (of M.I.T.). These examinations included X-ray diffraction analysis, differential thermal analysis, and transmission electron microscopy.

During the period December 1972 to October 1973, 93 lots were individually sampled and examined by X-ray diffractometry for the presence of asbestos minerals. No amphiboles or serpentine minerals were detected in any sample.

Beginning in October 1973, differential thermal analysis was added to our specified requirement. Both, differential thermal analysis and X-ray diffractometry were instituted for the routine examination of sequential lots. A further 100 lots have since been examined, applying both methods to each sample. Again, no amphibole or serpentine minerals have been detected.

I would like to advise that we are continuing to employ differential thermal analysis and X-ray diffractometry in the examination of sequential lots for the detection of amphibole and serpentine minerals.

It should be pointed out that we also maintain a worldwide monitoring of talcs used by our Johnson & Johnson affiliates, employing these same techniques.

Finally, let me add that periodically, we also submit sub-samples for Transmission Electron Microscope examination and these have always verified the absence of asbestiform minerals.

It is our understanding that you would wish to submit this information to the FDA. Please regard this letter as non-confidential.

Sincerely yours,

George Lee
Director of Applied Research

GL/mm

WCD0000009.

Exhibit 144

JNJ000268964

Metadata

Confidentiality	Y	ORIGINAL
Custodian	Legacy 1	ORIGINAL
DocumentType	Physical	ORIGINAL

Dr. W. Nashed
Dr. T. H. Shelley
Dr. G. Hildick-Smith

Johnson & Johnson

1503
New Brunswick, N.J.
December 13, 1972

Subject: Meeting November 1, 1972
with Dr. Schaffner - F. D. A.

Talc File:

I met with Dr. Schaffner on November 1 and we had a frank, friendly talk for approximately an hour. I explained my mission and the necessity to make clear the concern of Johnson & Johnson management with respect to Dr. Lewin's report. I explained that from the beginning our company's attitude and actions had been to share information with the FDA in order to prevent unnecessary panic and irrational actions due to any ill-informed consumer pressures. We had, I pointed out, provided information and offered our complete background files to the administration prior to the public disclosures in this country of any concerns about talc per se or the potential contamination of talc with asbestos.

I pointed out that having listened to Dr. Lewin and to the presentations of the world authorities we had assembled as consultants, I was convinced that there wasn't a shred of evidence to support the idea that either our Johnson* Baby Powder or Shower to Shower* contained any chrysotile asbestos. I said it was therefore difficult for me to explain to my colleagues in Johnson & Johnson management why it had not been decided not to publish Dr. Lewin's report. I then concluded that unless he could assure me that the report would not be issued I was instructed to make an appointment with Commissioner Edwards and make our viewpoint known to him. We felt this was necessary to be assured that the seriousness with which we view this situation and its potential effect on our business was known at all levels of the administration so that it could be viewed in the light of any consumer pressures.

Dr. Schaffner did not disagree with me and repeated that he had not seen the report on our Baby Powder samples which had obviously irritated him. He agreed that we had indeed assembled competent people and appeared sympathetic to our views. He asked how much we had spent and I gave him a reasonable estimate. He told me confidentially and asked that I not publicize it, that he had received a comment from an optical microscopist on the FDA staff in a discussion of another problem, that Dr. Lewin was wrong and that he was "outside his field of competence". I confirmed that that was our view and that of our consultants. He went on to say that he had asked the Bureau of Mines "as suggested

- 2 -

Meeting November 1, 1972
with Dr. Schaffner - FDA

December 13, 1972

by Dr. Nashed" to review this report, but so far he had not heard from them. He said "I have no control over the Bureau of Mines, I cannot guarantee when they will report", but he hoped that it would be completed within two weeks.

He went on to say that he was not happy that Lewin's work had now turned into a research project on a new theory of structure and not a program for the definition of analytical procedures as we had all envisioned it to be. We agreed that we had both expected the McCrone and Lewin conference to settle the problem.

When I pressed for an assurance that the report would not be issued he said "it would be issued only over my dead body". He then discussed with me what he said was his problem of what to do with the report with respect to other manufacturers' products if our products were cleared on the basis of our work and presentation. He was afraid of being accused of favoritism to the large corporation, as they apparently were in the case of Bon Vivant Soup Company in relation to Campbell Soup. While he emphasized that this was his problem and not mine, he was interested in any comment that I would care to make. I suggested that since the controversy over Dr. Lewin's report centered around the analytical procedures used, that if our work (as I was confident it did) showed this to be invalid for our products, it obviously had to be invalid for the products of other manufacturers as well. I suggested that I thought it would be necessary to reanalyze the talcs by the accepted procedure that was worked out in our meeting.

Dr. Schaffner asked what I thought about tremolite and I responded that there was no evidence to implicate it as a carcinogen. He said he agreed with me and that they had searched the literature without success to find any report on the toxicity of tremolite. I said that I believed we had an article or two when tremolite had been used and found free of toxic effects (including carcinogenicity). I said that I would forward any references we had to him and he said that would be very helpful.

Dr. Schaffner then switched the subject to that of toxicity of talc per se. He said that there was pressure on the F. D. A. with respect to banning talc. When I asked if these pressures were generalized or if he could give specific samples he quoted from a

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letter from a Mr. Fred C. Hart of the Department of Air Resources in New York City. The letter dealt with the use of talc containing asbestos in packaging materials and food additives and recommended its banning. The reasons given were some that we have heard before, mainly inuendo without any real facts to back them up. The letter further suggested that cosmetics probably should be included in the ban as well. (Dr. Nash would you please check to see if we can get a copy of Mr. Hart's letter the one dated September 18, 1972). Dr. Schaffner indicated that he believed it was on file with the Hearing Clerk. I told Dr. Schaffner we had a good deal of information on the freedom from toxicity on talc both from the literature and from some in house studies. He wanted to know if we would discuss this subject with some members of his staff and I agreed to do so. I told him that while much of this information was already organized into a report it would be better if we could postpone such a meeting until our work was completed and I guessed that this might be as early as two weeks but I couldn't be positive. I told him that should any emergency arise due to some incident or consumer pressure before our meeting with him, not to hesitate to call us. I said that Dr. Hildick-Smith would be prepared to discuss this subject with with them on a few hours notice.

Dr. Schaffner then concluded our meeting by suggesting that he call me in two weeks when he hoped to have his decision on Lewin's report finalized. If he did not have the necessary information from the Bureau of Mines and therefore could not give us the answer he would make an appointment for Mr. Smoyer and I to see Commissioner Edwards. I suggested that when he called we could perhaps set the date for our meeting to discuss the toxicity of talc. I thanked him for his providing the time for our meeting and we parted in a very friendly way.


R. A. Fuller